Proposed Re-evaluation Decision PRVD2015-07

# Deltamethrin

*(publié aussi en français)* **31 December 2015**

This document is published by the Health Canada Pest Management Regulatory Agency. For further information, please contact:

Publications
Pest Management Regulatory Agency
Health Canada
2720 Riverside Drive
A.L. 6607 D
Ottawa, Ontario K1A 0K9

Internet: pmra.publications@hc-sc.gc.ca
healthcanada.gc.ca/pmra
Facsimile: 613-736-3758
Information Service:
1-800-267-6315 or 613-736-3799
pmra.infoserv@hc-sc.gc.ca

Canada

ISSN: 1925-0959 (print)
1925-0967 (online)

Catalogue number: H113-27/2015-7E (print)
H113-27/2015-7E-PDF (PDF version)

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# Overview

## Proposed Re-evaluation Decision for Deltamethrin

After a re-evaluation of the insecticide deltamethrin, Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of products containing deltamethrin for sale and use in Canada.

An evaluation of available scientific information found that products containing deltamethrin do not present unacceptable risks to human health or the environment when used according to the proposed label directions. As a condition of the continued registration of deltamethrin uses, new risk reduction measures are proposed for the end-use products registered in Canada.

This proposal affects the end-use products containing deltamethrin registered in Canada.Once the final re-evaluation decision is made, the registrant will be instructed how to address any new requirements.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for deltamethrin and presents the reasons for the proposed re-evaluation decision. It also proposes new risk reduction measures to further protect human health and the environment.

The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides detailed technical information on the assessment of deltamethrin.

The PMRA will accept written comments on this proposal up to 60-days from the date of publication of this document. Please forward all comments to Publications (please see contact information indicated on the cover page of this document).

## What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2012-02, *Re-evaluation Program Cyclical Re-evaluation*, presents the details of the current re-evaluation approach.

For more details on the information presented in this overview, please refer to the Science Evaluation of this consultation document.

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[1] "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*

## What is Deltamethrin?

Deltamethrin is a synthetic pyrethroid insecticide used to control a broad range of arthropod pests on a wide variety of sites including greenhouse ornamentals, greenhouse food crops, industrial oilseed crops, terrestrial feed crops, terrestrial food crops, roadsides, shelterbelts and turf. It is applied by farmers, farm workers and professional applicators, using conventional aerial equipment (rotary and fixed wing aircraft) and conventional ground equipment such as boom sprayers, airblast sprayers, mist blowers and hand held sprayers.

## Health Considerations

### Can Approved Uses of Deltamethrin Affect Human Health?

**Products containing deltamethrin are unlikely to affect your health when used according to the proposed label directions, which include additional risk reduction measures.**

Potential exposure to deltamethrin may occur through diet or when handling and applying products containing deltamethrin. When assessing health risks, two key factors are considered: the levels where no health effects occur in animal testing and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

Toxicology studies in laboratory animals describe potential health effects from varying levels of exposure to a chemical and identify the dose where no effects are observed. The health effects noted in animals occur at doses which are much higher than levels to which humans are normally exposed when pesticide products are used according to label directions.

In laboratory animals, acute oral toxicity of deltamethrin ranged from low to high, depending on the vehicle used. Deltamethrin is of low to moderate acute inhalation toxicity, and is of low acute dermal toxicity. Deltamethrin is not an eye or skin irritant. Exposure to deltamethrin is not expected to cause an allergic skin reaction, however itching, tingling or burning sensations of the skin may occur.

Registrant-supplied short, and long term (lifetime) animal toxicity tests, as well as numerous peer-reviewed studies from the published scientific literature were assessed for the potential of deltamethrin to cause neurotoxicity, immunotoxicity, chronic toxicity, cancer, reproductive and developmental toxicity, and various other effects. The most sensitive endpoint used for risk assessment was neurotoxicity characterized by a reduced reflex response in young animals. There is some indication that the young may be more sensitive than the adult animal; this sensitivity may reflect age-dependent differences such as the maturation of key metabolic processes.

The risk assessment protects against these and any other potential effects by ensuring that the level of exposure to humans is well below the lowest dose at which these effects occurred in animal tests.

### Residues in Food and Water

**Dietary risks from food and water are not of concern.**

Reference doses define levels to which an individual can be exposed over a single day (acute) or lifetime (chronic) and expect no adverse health effects. Generally, dietary exposure from food and water is acceptable if it is less than 100% of the acute reference dose (ARfD) or acceptable daily intake (ADI). An acceptable daily intake is an estimate of the level of daily exposure to a pesticide residue that, over a lifetime, is believed to have no significant harmful effects.

Dietary exposure was estimated for deltamethrin in its three isomeric forms, cis-, trans- and α-R which also comprise the residue definition. The assessment includes acute and chronic risk estimates from consumption of both food and water. The exposure assessment used monitoring residue data, field trial residue data, maximum residue limits (MRLs), 100% of treated crops, processing factors, anticipated residue for livestock, domestic and import supply data, water residue and residue trials for potential contamination of food from treatment of food handling establishments with deltamethrin.

The chronic exposure to deltamethrin from food and water ranges from 7% to 29% of the ADI for different sub-populations, with the highest value for children aged 1 to 2 years old. The acute exposure to deltamethrin from food and water ranges from 19% to 66% of the ARfD (deterministic estimate at the 95th percentile) for different sub-populations, with the highest value for children aged 1 to 2 years old. Based on the above results, acute and chronic dietary risks to deltamethrin are not of concern.

The *Pest Control Products Act* prohibits the sale of adulterated food; that is, food containing a pesticide residue that exceeds the established MRL. Pesticide MRLs are established through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value defines the maximum concentration in parts per million (ppm) of a pesticide allowed in or on certain foods. Food containing a pesticide residue that is at or below the established MRL does not pose an unacceptable health risk.

MRLs for deltamethrin are currently specified for a wide range of commodities. Where no specific MRL has been established, a default MRL of 0.1 ppm applies, which means that pesticide residues in a food commodity must not exceed 0.1 ppm. The current MRLs for deltamethrin can be found in Appendix X of this document.

### Occupational Risks from Handling Deltamethrin

**Occupational risks to handlers are not of concern when used according to the proposed label directions, which include additional risk reduction measures.**

Occupational dermal exposure risks are not of concern as the risk estimates associated with mixing, loading, and applying activities exceeded target dermal margins of exposure (MOEs). The inhalation exposure risks are not of concern except for the use of mechanically pressurized handguns on shelterbelts where the target inhalation MOE was not met. However, with the addition of an approved respirator, the inhalation MOE for this scenario is not of concern.

**Postapplication risks are not of concern for all uses.**

Postapplication occupational risk assessments consider exposures to workers entering treated sites in agriculture. Based on the current use pattern for agricultural scenarios reviewed for this re-evaluation, postapplication risks to workers performing activitiessuch as thinning, pruning and scouting of crops are not of concern.

The PMRA is primarily concerned with the potential for dermal exposure for workers performing postapplication activities in crops treated with a foliar spray. Postapplication inhalation exposure is not considered to be a significant route of exposure as deltamethrin is relatively non-volatile with a low vapour pressure of $9.3 \times 10^{-11}$ mmHg at 25°C. Due to this, a postapplication inhalation exposure assessment was not required.

**Risks in Residential and Other Non-Occupational Environments**

**Non-occupational risks are not of concern when used according to label directions.**

Residential exposure may occur from the application of products containing deltamethrin to residential lawns and turf (including golf courses) by commercial applicators only. As there is no potential exposure to homeowners mixing, loading, and applying deltamethrin, only a residential postapplication risk assessment was required.

Residential postapplication exposure may occur while performing activities on treated areas, as well as golfing on treated golf course turf, following a commercial application of deltamethrin. Incidental oral exposure may also occur for children (1 to < 2 years old).

Residential postapplication activities met the target dermal MOE for all populations (including golfers) and are not of concern. For incidental oral exposure, the target oral MOE was met for children (1 to < 2 years old) and is not of concern.

Incidental oral exposure (hand-to-mouth) was aggregated with background (chronic) dietary exposure (food and drinking water). The resulting aggregate risk estimates exceeded the target MOE and are not of concern.

**Non-occupational risks from bystander dermal exposure are not of concern.**

Bystander exposure may occur when the general public enter non-cropland areas (for example, biking through forests or parks) that have recently been treated with deltamethrin. The resulting risk estimates associated with bystander dermal exposure exceeded the target MOE for all populations and are not of concern.

**Non-occupational risks from bystander drift are not of concern.**

Inhalation exposure is not considered to be a significant route of exposure as deltamethrin is relatively non-volatile with a low vapour pressure of $9.3 \times 10^{-11}$ mmHg at 25°C. Consequently, a quantitative bystander drift exposure assessment was not required.

## Environmental Considerations

### What Happens When Deltamethrin Is Introduced Into the Environment?

**When used according to the proposed label directions, deltamethrin is not expected to pose an unacceptable risk to the environment.**

When deltamethrin is released into the environment, it can enter soil and surface water where it can persist under certain conditions. In soil, deltamethrin binds strongly to soil particles, making it unlikely to move downward in the soil and reach groundwater. In aquatic environments, deltamethrin will rapidly move out of water and into the sediments where it can persist. Deltamethrin has not been detected in available Canadian surface and groundwater monitoring data.

Deltamethrin is known to move into the atmosphere but is unlikely to persist in air or move in air to remote locations such as the Arctic. Deltamethrin is not likely to accumulate in the tissues of organisms such as fish.

In laboratory studies deltamethrin was found to be toxic to bees, beneficial insects, mammals and aquatic organisms when exposed to high enough concentrations. Consequently, if deltamethrin is used at labelled application rates without any risk reduction measures, it may cause adverse effects in the organisms listed above. Therefore, risk mitigation measures in the form of use restrictions and precautionary label statements are proposed in order to minimize exposure and mitigate potential risks. For pollinators, risks are mitigated by restricting application to periods when bees are not actively foraging. The risk to aquatic organisms is mitigated with spray buffer zones and recommendations on the label to reduce runoff from fields. Toxicity statements are also proposed to protect beneficial insects and mammals. When deltamethrin is used in accordance with the label and the mitigation measures have been applied, the reduced environmental exposure is deemed adequate and the risk is considered to be acceptable.

There are currently no environmental incident reports involving deltamethrin in Canada.

## Value Considerations

### What is the Value of Deltamethrin?

**Deltamethrin is a broad-spectrum insecticide that controls numerous insect pests in many crops.**

It is currently registered for use on field, greenhouse and orchard crops, greenhouse ornamentals, roadsides, shelterbelts and turf for the control of numerous insect pests. These include weevils, cutworms, beetles, moths, aphids, tent caterpillars, leafrollers, webworms, corn borers, earworms and grasshoppers. Deltamethrin contributes to resistance management by helping to delay the development of resistance when used in rotation with other insecticides with different modes of action.

## Proposed Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. Following these directions is required by law. As a result of the re-evaluation of deltamethrin, the PMRA is proposing further risk-reduction measures in addition to those already identified on deltamethrin product labels.

The additional risk-reduction measures are discussed below.

### Human Health

To protect mixer/loader/applicators, the following requirement is proposed to be added to all agricultural labels:

- Workers must wear a respirator with either a NIOSH approved organic vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH approved canister approved for pesticides when mixing, loading, and applying deltamethrin using mechanically pressurized handgun equipment.

To protect workers entering treated sites, the following requirement is proposed to be added to all agricultural labels:

- Restricted-entry Interval (REI) is 12 hours after application for all agricultural uses.

To protect bystanders, the following requirement is proposed to be added to all commercial labels:

- Apply only when the potential for drift to areas of human habitation or areas of human activity (houses, cottages, schools and recreational areas) is minimal. Take into consideration wind speed, wind direction, temperature inversion, application equipment and sprayer settings.

To protect homeowners, the following requirement is proposed to be added to all commercial labels:

- Not for use by homeowners or other uncertified users.

As there are no registered products that use fogging or misting applications (automated and/or manual) in greenhouses, the following statement is proposed to be added to all agricultural labels:

- Not permitted for application using a handheld mist blower and/or fogger machine (handheld and automated) in greenhouses.

**Environment**

- Environmental hazard statements for bees, beneficial insects, mammals and aquatic organisms are proposed.

  Spray buffer zones for non-target aquatic habitats are proposed for deltamethrin. The PMRA is in the process of revising its approach to buffer zones for all chemicals and will consult broadly on the revised approach prior to implementation. The buffer zone requirements proposed in this document are based on the PMRA's current approach. Buffer zones identified in this proposed decision document may be revised based on any new information received and on any future revisions to the Agency's approach to calculating buffer zones.
- A label statement advising that the application of deltamethrin should be restricted to periods when pollinators are not actively foraging is proposed.

- To reduce the potential for runoff of deltamethrin to adjacent aquatic habitats, precautionary statements for sites with characteristics that may be conducive to runoff and when heavy rain is forecasted are proposed. In addition, a vegetative strip between the treatment area and the edge of a water body is recommended to reduce runoff of deltamethrin to aquatic areas.

## Next Steps

Before making a final re-evaluation decision on deltamethrin, the PMRA will consider all comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on deltamethrin. The PMRA will then publish a Re-evaluation Decision[5] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA's response to these comments.

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[5] "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

# Science Evaluation

## 1.0 Introduction

Deltamethrin is under re-evaluation in Canada as announced by the PMRA in the 20 December 2011 Re-evaluation Note *REV2011-05, Re-evaluation of Pyrethroids, Pyrethrins and Related Active Ingredients*. Deltamethrin is a broad spectrum contact insecticide belonging to the Resistance Management Mode of Action (MoA) group 3A. Deltamethrin acts on the nervous system of insects, and disturbs the function of neurons by interaction with sodium channels. It works by contact and stomach action, and is fast acting.

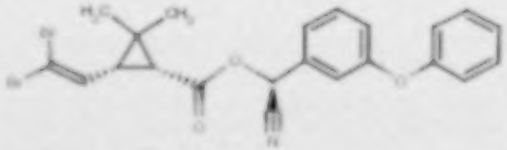
Following the re-evaluation announcement for deltamethrin, Bayer Canada Inc. the registrant of the technical grade active ingredient and primary data provider in Canada, indicated that it intended to provide continued support for all uses included on the label of commercial class end-use products. There are no domestic class end-use products.

## 2.0 The Active Substance, its Properties and Uses

### 2.1 The Technical Grade Active Ingredient, Its Properties and Uses

### 2.2 Identity of the Technical Grade Active Ingredient

| | | |
|---|---|---|
| **Common Name** | | Deltamethrin |
| **Function** | | Insecticide |
| **Chemical Family** | | Pyrethroid |
| **Chemical Name** | | |
| 1 | **International Union of Pure and Applied Chemistry (IUPAC)** | (*S*)-α-cyano-3-phenoxybenzyl (1*R*,3*R*)-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylate |
| 2 | **Chemical Abstracts Service (CAS)** | (*S*)-cyano(3-phenoxyphenyl)methyl (1*R*,3*R*)-3-(2,2-dibromoethenyl)-2,2-dimethylcyclopropanecarboxylate |
| **CAS Registry Number** | | 52918-63-5 |
| **Molecular Formula** | | $C_{22}H_{19}Br_2NO_3$ |

| | |
|---|---|
| **Structural Formula** |  |
| **Molecular Weight** | 505.2 |
| **Purity of the Technical Grade Active Ingredient** | 99.5% nominal (limits: 98.5-100%) |
| **Registration Number** | 18092 |

Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the product.

## 2.3 Physical and Chemical Properties of the Technical Grade Active Ingredient

| Property | Result |
|---|---|
| Vapour pressure at 25°C | $1.24 \times 10^{-5}$ mPa |
| Ultraviolet (UV)/visible spectrum | Not expected to absorb at $\lambda > 300$ nm |
| Solubility in water at 25°C | $< 0.2$ μg /L |
| n-Octanol/water partition coefficient at 25°C | $\log K_{ow} = 4.6$ |
| Dissociation constant | Not applicable |

## 2.4 Description of Registered Deltamethrin Uses

Appendix I lists all deltamethrin products that are registered under the authority of the *Pest Control Products Act*. Appendix II lists all the uses for which deltamethrin is registered. All uses were supported by the registrant at the time of re-evaluation initiation and were therefore considered in the health and environmental risk assessments of deltamethrin.

Uses of deltamethrin belong to the following use-site categories: greenhouse food and non-food crops, industrial oil seed and fibre crops, terrestrial feed and food crops, industrial and domestic vegetation control for non-food sites, ornamentals and turf, including golf courses, residential lawns and sod farms.

## 3.0 Impact on Human and Animal Health

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels where no effects are observed. Unless there is evidence to the contrary, it is assumed that effects observed in animals are relevant to humans and that humans are more sensitive to effects of a chemical than the most sensitive animal species.

### 3.1 Toxicological Summary

An extensive toxicology database is available for assessment of human health risks of deltamethrin and data quality is considered adequate to characterize toxicological hazards.

Deltamethrin is a broad spectrum pyrethroid insecticide. Pyrethroids are believed to induce neurotoxic effects primarily by binding to voltage-dependant sodium channels in neurons, thereby delaying the closing of sodium channels and causing the depolarization of neurons. This affects action potentials and results in repetitive activity (Type I pyrethroids) or blockage of nerve conduction (Type II pyrethroids). Deltamethrin, a pyrethroid containing a cyano group, is a Type II pyrethroid. Type II pyrethroids induce the "CS syndrome", characterized by choreoathetosis (involuntary excessive movements progressing to sinuous writhing), sedation, salivation, dyspnoea, clonic seizures and body tremors.

Technical grade deltamethrin contains more than 98% cis-deltamethrin. The parent compound (cis-deltamethrin) and its isomers, trans-deltamethrin and α-R-deltamethrin, are major residues in plants and are considered chemicals of concern for human health risk assessment purposes. Although there are no toxicity data available for the trans- or α-R isomers, these compounds are assumed to have equivalent toxicity to that of cis-deltamethrin based on knowledge of pyrethroids. Major metabolites of deltamethrin which have been detected in mammals appear to be less toxic than the parent compound. Deltamethrin is produced as a degradation product of another pyrethroid, tralomethrin. Tralomethrin is structurally similar to deltamethrin and shares the same major metabolites in vivo. Tralomethrin was registered in Canada as a manufacturing concentrate for export, but registration expired in 2011.

Pharmacokinetic data for deltamethrin are based on radiolabelling studies in which experimental animals were exposed to single or repeated oral doses. In rats and mice, absorption of deltamethrin from the gastrointestinal tract was rapid, with blood concentrations reaching peak levels 1 to 2 hours following exposure. The rate and extent of oral or dermal absorption was strongly dependent on the vehicle used but overall, bioavailability was low. The tissue concentration of deltamethrin was dose-dependent following oral exposure. Following single or repeated exposure in rodents, the highest tissue residues were detected in fat. In general, higher tissue levels were noted in rats receiving a single high dose, compared to animals receiving a single low dose or repeated low doses. Low concentrations of deltamethrin were detected in adipose tissue seven days following acute or repeated oral exposure in rats. Based on studies in rats, only a small proportion (0.1%-0.3%) of the absorbed oral dose reaches the brain. The blood-brain barrier and the phospholipid composition of the brain may be factors in the limited partitioning of highly lipophilic deltamethrin. Once in the brain, deltamethrin was eliminated slowly, with elimination half-lives in adult rat brain tissue ranging from 12.5 to 19.5 hours. Acute oral exposure in pre-weanling, weanling and adult rats resulted in tissue concentrations and neurological effects, the severity of which was inversely related to age. In this study, brain tissue concentrations in pre-weanling and weanling rats were up to 4-fold higher than brain tissue concentrations in adults receiving the same acute dose. Also, brain concentrations in young animals were elevated for a longer time relative to adults. Elimination half-lives in the brain tissue of young rats (Post Natal Day (PND) 10, 21 or 40) ranged from 22.5 to 32.6 hours.

In rodents, the elimination of deltamethrin via urine and feces was rapid and extensive despite delayed elimination from fat, skin and skeletal muscle, relative to other tissues. Deltamethrin was completely eliminated from the body within 6-8 days following oral exposure. Deltamethrin was extensively metabolized in rodents by two major pathways. The first pathway involves hepatic oxidation of deltamethrin by cytochrome P450 oxidase to (2', 4' or 5')-hydroxy-deltamethrin, followed by ester-mediated hydrolysis to 3-(2', 4' or 5'-hydroxyphenoxy)-benzoic acid, and conjugation with sulphate and glucuronide. The second metabolic pathway involves hydrolysis of deltamethrin by carboxylesterases in plasma and liver to 3-phenoxybenzoic acid, followed by conjugation with sulphate and glucuronide. The metabolism of deltamethrin is an important determinant of its neurotoxicity, since the pyrethroid structure of the parent compound is the most neuroactive form (USEPA, 2003). Substances which inhibit liver microsomal oxidase or carboxylesterase enzyme systems will decrease the metabolism of deltamethrin, and thus increase the potential for neurotoxic effects. Metabolic clearance of deltamethrin in rats increases during maturation, primarily due to increased hepatic enzyme activity. Although the metabolic pathways in rats and mice are similar, there are some species-related quantitative differences. For example, rats produce more phenolic metabolites than mice, while mice produce more trans-hydroxymethyl cyclopropanecarboxylic acid than rats.

Deltamethrin was of low to high acute oral toxicity in rats, depending on the vehicle used. Clinical signs were characteristic of disruption of the autonomic nervous system and indicative of the "CS syndrome", including excessive salivation, decreased activity, labored breathing, drooping eyelids, stained fur, excessive grooming, drowsiness, motor incoordination, choreoathetosis, clonic seizures and death. No significant sex-related differences in toxicity were noted in animals exposed to acute doses. In an acute oral comparative neurotoxicity study, pup and weanling rats were up to 16-fold more sensitive to mortality than adults, based on $LD_{50}$ values. In acute dermal studies, deltamethrin was of low acute toxicity in rats, and did not induce clinical signs of neurotoxicity following administration of high dermal doses. Deltamethrin induced low to moderate acute inhalation toxicity in rats, was not an eye or skin irritant in rabbits, and was not a dermal sensitizer in guinea-pigs.

In (supplemental) short-term dietary studies in mice, mortality and decreased body weight were the critical toxicological effects, with neurotoxicity noted in mice at high oral doses. In short-term oral toxicity studies in other species, the critical effects at low oral doses were decreased body weight in rats and neurotoxicity in dogs, as indicated by tremors, posture and gait abnormalities, splayed limbs, decreased reflex reactions and paresthesia. At higher subchronic oral doses, neurotoxicity and mortality were also noted in rats.

Neurotoxic signs were reported in rats following short-term (whole-body) inhalation exposure to very low concentrations of deltamethrin aerosol. In contrast, no adverse toxicological effects were noted in rats following short-term dermal exposure to deltamethrin in polyethylene glycol at the limit dose.

In an acute oral comparative neurotoxicity study, weanling and adult rats exposed to deltamethrin by gavage demonstrated a decrease in acoustic startle response amplitude at the lowest administered dose. Salivation, burrowing behavior and spontaneous vocalizations were noted in weanlings, while similar effects were noted in adults at a higher oral dose. In this study, brain tissue concentrations of deltamethrin were 2-fold higher in weanling rats, compared to adults receiving the same dose, suggesting that young animals have a limited capacity to metabolize and eliminate deltamethrin compared to adults. While pyrethroids are metabolized by a variety of esterases and oxidases, the α-cyano substituent of deltamethrin impedes metabolism and may make the immature rat, with relatively limited metabolic capacity, particularly sensitive to deltamethrin.

The results of other acute or repeat-dose oral neurotoxicity studies in rats demonstrated mortality, decreased body weight, salivation, drooping eyelids, tremors, decreased motor activity, altered posture and mobility, low arousal, decreased limb grip strength, impaired gait, muscular rigidity, piloerection and convulsions. Sensitivity of the young was noted in a developmental neurotoxicity study conducted in rats, in which neurotoxic signs were observed in offspring, but not dams exposed to deltamethrin. No microscopic neuropathology was evident in rats exposed orally to deltamethrin in neurotoxicity studies conducted up to 13-weeks.

In 2-year dietary studies, neurotoxicity was evident in mice (dermal responses related to paresthesia), rats (gait and postural abnormalities) and dogs (absent blink reflex). Although the absent blink reflex in dogs was the most sensitive endpoint in the database, available dose-response data for this endpoint were not considered adequately robust for risk assessment purposes. Further, this effect was not reproducible in a 1-year oral toxicity study in dogs conducted at 50-fold higher doses, there was no supporting evidence of visual impairment (including altered activity level, posture, gait, pupil reflex, visual placing reflex or righting reflex) at doses which induced absent blink reflex, and there was no pathology involving the eye or associated neural pathways in the database.

Neurotoxicity did not increase with increasing duration of oral exposure to deltamethrin, likely due to the rapid metabolism and elimination of this compound. Systemic effects including reduced body weight (mice, rats, dogs), organ weight changes (mice), hepatotoxicity (rats) and mortality (mice, rats) were also noted in repeat-dose oral studies, though at doses greater than those associated with neurotoxicity in dogs (repeated exposure) and rats (acute exposure). No gross or microscopic neuropathology was observed in repeat-dose oral studies in rodents or dogs.

Deltamethrin did not increase the incidence of tumours in rodents, based on adequate long-term dietary studies in mice and rats.

The results of genotoxicity studies were negative. Within in vitro studies, deltamethrin was neither mutagenic nor clastogenic, and did not induce unscheduled DNA synthesis in cultured mammalian cells. In in vivo studies conducted in mice exposed by gavage (in oil), deltamethrin did not induce dominant lethal mutations, and did not induce micronuclei or chromosomal aberrations in bone marrow cells.

In a 2-generation reproductive toxicity study in rats, there was no evidence of adverse effects on mating performance or fertility. However, there was qualitative sensitivity of the young based on effects in $F_1$ offspring (cerebral congestion, blood clots in the brain, neurotoxic signs) which were considered more serious than those observed in $F_0$ parental animals (reduced body weight) receiving the same dose. The incidence of mortality was also increased in $F_1$ offspring, relative to $F_0$ parental animals. Effects on male reproductive organ weights were noted in $F_0$ and $F_1$ at termination.

In developmental toxicity studies, deltamethrin did not induce teratogenic effects in mice, rats or rabbits following gavage administration (in oil or carboxymethylcellulose) of maternally-toxic doses. Decreased fetal body weight (mice, rabbits) and delayed ossification (mice) were observed in the absence of maternal toxicity in some studies. Wrist flexure (rabbits) and delayed ossification (rats, rabbits) were also noted in the presence of maternal toxicity. In a supplemental developmental toxicity study, oral exposure in rat dams during development and weaning produced male offspring with altered sperm production, decreased testosterone levels and altered reproductive organ weights, in the absence of maternal toxicity.

Pregnant females may be more sensitive than non-pregnant females to the lethal effects of gavage dosing with deltamethrin. Mortality was observed after 2 days of dosing at lower oral doses in rat dams in a developmental toxicity study (11 mg/kg bw/day), compared to non-pregnant females (≥ 50 mg/kg bw/day) receiving deltamethrin in acute gavage neurotoxicity studies using similar vehicles and routes of exposure. It is noteworthy, however, that different test strains were used in these studies, and mortality results may not be directly comparable.

Results of the toxicology studies conducted on laboratory animals with deltamethrin are summarized in Table 1 of Appendix III. The toxicology endpoints for use in the human health risk assessment are summarized in Table 2 of Appendix III.

### Risk Characterization

### *Pest Control Products Act* Hazard Characterization

For assessing risks from potential residues in food or from products used in or around homes or schools, the *Pest Control Products Act* requires the application of an additional 10-fold factor to threshold effects to take into account the completeness of the data with respect to the exposure of, and toxicity to, infants and children as well as potential pre- and post-natal toxicity. A different factor may be determined to be appropriate on the basis of reliable scientific data.

With respect to the completeness of the toxicology database for the assessment of risk to infants and children, the required studies for risk assessment were available. The database contains a range of adequate studies including oral developmental toxicity studies in mice, rats and rabbits, a 2-generation reproductive toxicity study in rats, a comparative acute oral neurotoxicity study and a developmental neurotoxicity study in rats.

With respect to identified concerns relevant to the assessment of risk to infants and children, the young may be more susceptible to deltamethrin, compared to adults, based on evidence of higher and prolonged brain concentrations in young animals, compared to adults, exposed to low oral doses. In the comparative acute oral neurotoxicity study, there was quantitative sensitivity in weanling rats to the lethal effects of deltamethrin, compared to adults, based on $LD_{50}$ values. In the reproductive toxicity study, there was qualitative sensitivity of the young with greater neurotoxicity and mortality in $F_1$ offspring compared to $F_0$ parental animals at the same dose level. The young animals appeared to be most vulnerable early in the post-weaning phase. This vulnerability could, in part, reflect greater bioavailability of deltamethrin associated with direct consumption of treated diet. In some developmental toxicity studies, delayed ossification in mice and decreased fetal body weight in mice and rabbits were observed in the absence of maternal toxicity, while in other studies, no developmental effects were observed. In a supplemental oral developmental toxicity study in rats, reproductive effects in male offspring were observed in the absence of maternal toxicity. Qualitative sensitivity of the young was observed in the rat developmental neurotoxicity study, as characterized by neurotoxic signs in offspring, but not dams exposed to the same oral dose of deltamethrin.

Although age-dependent sensitivity has been demonstrated with deltamethrin, some research suggests that this sensitivity is associated only with high doses. In an acute neurotoxicity study conducted with low dose levels, 21-day old weanling rats exhibited a similar response to acoustic startle response as adult rats despite having a higher concentration of deltamethrin in the brain. It is likely that metabolic clearance mechanisms (i.e., carboxylesterase and P450 enzymes) are not sufficiently developed in the young animal leading to accumulation, and at high levels, increased toxicity.

Acoustic startle response was identified as the most sensitive neurobehavioural endpoint in the available deltamethrin database. However, there is some concern that the critical study assessing this endpoint may underestimate the susceptibility of young rats. Validation data were not presented in the study report for the "time-of-peak-effect" used to assess acoustic startle response in pups (adults and pups were both assessed 2 hours post-exposure). Indeed, the same authors used a "time-of-peak-effect" of 1.5 hours for assessment of acoustic startle response in an earlier study of deltamethrin toxicity in the same strain of adult rats (Crofton and Reiter, 1984). Further, the use of older pups (PND 21) in the critical study may be less than ideal for representing the most susceptible human life stage. It should be noted that the SAP (2010) concluded that acoustic startle response is not the best measure for juvenile sensitivity because the response itself varies with age. While improved measures may be available in the future, acoustic startle response remains the best measure of juvenile sensitivity at this time.

There is also some concern regarding the seriousness of the critical neurobehavioral endpoint. While acoustic startle response is known to represent a reflex involving sensory and muscular systems, there is also a cognitive component. Thus, a treatment-related alteration in acoustic startle response may manifest as a wide range of neurotoxic effects in humans. It is not known how serious such effects may be in a developing human. Therefore, on the basis of residual uncertainty regarding the method of assessment of acoustic startle response in the critical study, the sensitivity of the endpoint and the seriousness of the endpoint, the *Pest Control Products Act* factor has been retained but reduced to threefold for risk assessments employing this endpoint (oral and inhalation exposure).

For risk assessments not employing the acoustic startle response endpoint (dermal), potential age susceptibility was an important consideration. The dermal study was conducted in adult animals. Given the known susceptibility of the young animal with oral dosing (higher and prolonged brain concentrations, compared to adults), there is uncertainty as to whether the young would be more susceptible than adults following dermal exposure. Furthermore, the most sensitive endpoints identified with oral dosing (motor activity and acoustic startle response) were not measured in the dermal study. In light of these uncertainties, a 10-fold *Pest Control Products Act* factor has been applied for dermal risk assessment for concerns relating to lack of testing in a susceptible population (the young), as well as concerns regarding the sensitivity of the measured endpoints in the dermal study.

## 3.2 Occupational and Non-Occupational Risk Assessment

Occupational and non-occupational risk is estimated by comparing potential exposures with the most relevant endpoint from toxicology studies to calculate a margin of exposure (MOE). This is compared to a target MOE incorporating uncertainty factors protective of the most sensitive subpopulation. If the calculated MOE is less than the target MOE, it does not necessarily mean that exposure will result in adverse effects. However, MOEs less than the target MOE require measures to mitigate (reduce) risk.

### 3.2.1 Toxicology Endpoint Selection for Occupational and Non-Occupational Risk Assessment

**Dermal Exposure**

For short-, intermediate- and long-term dermal risk assessment for the general population (including pregnant women, infants and children), the No Observed Adverse Effect Level (NOAEL) of 1000 mg/kg bw/day in rats in the three-week dermal toxicity study was selected. For residential scenarios, a target MOE of 1000 was derived, which includes uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and a 10-fold *Pest Control Products Act* factor (as outlined in the *Pest Control Products Act* Hazard Characterization section). For occupational exposure scenarios, the target MOE of 1000 includes uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and a 10-fold factor for concerns relating to lack of testing in a susceptible population (the young) as well as concerns regarding the sensitivity of the measured endpoints in the dermal study (for example, motor activity and acoustic startle response were not assessed).

### Inhalation Exposure

The most appropriate study for short-, intermediate- and long-term inhalation risk assessment for the general population (including pregnant women, infants and children) was the acute oral comparative neurotoxicity study in rats, in which a Lowest Observed Adverse Effect Level (LOAEL) of 1 mg/kg bw was determined in weanling rats based on reduced acoustic startle response. This LOAEL was selected since it is based on the most sensitive endpoint in the database. Data were not sufficient to support a benchmark dose for this endpoint. This LOAEL is supported by the results of the short-term inhalation toxicity study in adult rats in which a LOAEL of 0.78 mg/kg bw/day was derived based on minimal effects on body weight and clinical signs at the lowest tested dose. The inhalation toxicity study was not used as the critical study for risk assessment since the clinical signs may have been attributable to a physical response to the dust (for example, blinking, licking) rather than chemical toxicity *per se*. Furthermore, the results of the inhalation toxicity study may be confounded by the whole-body exposure. A target MOE of 300 was selected, which includes uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and 3-fold to account for concerns outlined in the *Pest Control Products Act* Hazard Characterization section. An additional uncertainty factor for lack of a NOAEL was not required since the extent of change (18% decrease) in acoustic startle response was considered to be close to the response threshold.

### Non-Dietary Incidental Oral Ingestion

For assessment of non-dietary (incidental) oral exposure (up to 6 months), the LOAEL of 1 mg/kg bw based on reduced acoustic startle response in weanling rats in the acute oral comparative neurotoxicity study was selected. This acute LOAEL was selected since it is the most sensitive endpoint in the database; neurotoxicity does not increase with increasing duration of exposure, and the LOAEL is protective of other neurological and systemic effects. A target MOE of 300 was selected based on uncertainty factors of 10-fold for interspecies extrapolation, 10-fold for intraspecies variability and a 3-fold *Pest Control Products Act* factor (see *Pest Control Products Act* Hazard Characterization section). An additional uncertainty factor for lack of a NOAEL was not required since the LOAEL was determined to be close to the response threshold.

### Cancer Assessment

Deltamethrin did not increase the incidence of tumours in rodents, based on adequate long-term dietary studies in mice and rats.

### Dermal Absorption

As the toxicological endpoint for the short- intermediate- and long-term dermal risk assessments are based on a NOAEL from a dermal toxicity study, no dermal absorption factor was required for the risk assessment.

### 3.2.2 Occupational Exposure and Risk Assessment

Workers can be exposed to deltamethrin through mixing, loading or applying the pesticide, and/or when entering a treated site to conduct activities such as scouting and/or irrigating treated crops.

#### Mixer, Loader, and Applicator Exposure and Risk Assessment

There are potential exposures to mixers, loaders, applicators, or other handlers. The following scenarios were assessed, as they are supported by the registrant:

- Mixing/loading of liquids
- Groundboom, aerial and/or airblast application of liquids
- Mixing, loading, and applying liquids with mechanically pressurized handgun, manually pressurized handwand, right-of-way sprayer, and/or backpack equipment.

Farmers and commercial applicators may handle deltamethrin for short to intermediate periods of time. Therefore, most applicators have the potential for short-term (1-30 days) exposure with the exception of custom applicators where a higher number of applications are possible; these scenarios were considered to have intermediate-term exposure (30 days to <6 months). Long-term exposure (>6 months) was assumed for indoor uses of deltamethrin on greenhouse tobacco and ornamentals, as the growing season is typically all year long, as well as multiple/staggered crop cycles are possible.

The exposure estimates for mixer/loaders and applicators are based on the following scenarios with regards to personal protective equipment (PPE) and engineering controls:

- Baseline PPE - Long pants, long-sleeved shirt and chemical-resistant gloves (unless specified otherwise). For groundboom and aerial application, this scenario does not include gloves, as the data quality was better for non-gloved scenarios than gloved scenarios.
- Respirator - A respirator with NIOSH approved organic-vapour removing cartridge with a prefilter approved for pesticides or a NIOSH approved canister approved for pesticides.

Dermal and inhalation exposures were estimated using data from the *Pesticide Handlers Exposure Database* (PHED), *Version 1.1*. The PHED is a compilation of generic mixer/loader applicator passive dosimetry data with associated software which facilitates the generation of scenario-specific exposure estimates based on formulation type, application equipment, mix/load systems, and level of personal protective equipment (PPE). In most cases, PHED did not contain appropriate data sets to estimate exposure to workers wearing a respirator. As necessary, PHED unit exposures were adjusted by a protection factor (PF) of 90% for the use of a respirator.

The calculated dermal MOEs are greater than the target MOEs for all scenarios using maximum rates and baseline PPE.

The calculated inhalation MOEs are greater than the target MOE for all scenarios except for mechanically pressurized handgun use on shelterbelts. The addition of an approved respirator and its corresponding protection factor of 90% results in an inhalation MOE which exceeds the target MOE. This PPE (baseline plus respirator) is already present on 5 out of 6 of the deltamethrin end use product labels.

The mixer/loader/applicator exposure estimates are based on the best available data at this time. Route specific MOEs for mixer/loader and applicators for agricultural crops are outlined in Appendix IV, Tables 1 and 2.

**Postapplication Worker Exposure and Risk Assessment**

The postapplication occupational risk assessment considered exposures to workers who enter treated sites to conduct agronomic activities involving foliar contact (for example, pruning, thinning, harvesting, or scouting). Based on the deltamethrin use pattern, there is potential for short-, intermediate-, and long-term postapplication exposure to deltamethrin residues for postapplication workers.

Activity specific transfer coefficients (TC) were used to estimate postapplication exposure resulting from contact with treated turf and foliage at various times after application. A TC is a factor that relates worker exposure to dislodgeable residues. TCs are specific to a given crop and activity combination (for example, hand harvesting apples, scouting late season corn) and reflect standard clothing worn by adult workers. Postapplication exposure activities include (but are not limited to): scouting turf, as well as hand harvesting, transplanting, pinching, pruning, and thinning for ornamental and agricultural crops.

Dislodgeable foliar residue (DFR) and turf transferrable residues (TTR) refer to the amount of residue that can be dislodged or transferred from a surface, such as the leaves of a plant or turf. There were no chemical specific DFR) or TTR studies submitted to the PMRA for the re-evaluation of deltamethrin, so the following default values were used:

- A default peak value of 25% of the application rate with a dissipation rate of 10% per day was used for DFR estimates.
- A default peak value of 1% of the application rate with a dissipation rate of 10% per day was used for TTR estimates.

For workers entering a treated site, restricted-entry intervals (REIs) are calculated to determine the minimum length of time required before people can safely enter after application. An REI is the duration of time that must elapse before residues decline to a level where performance of a specific activity results in exposures above the target MOE.

The PMRA is primarily concerned with the potential for dermal exposure for workers performing postapplication activities in crops treated with a foliar spray. Deltamethrin is relatively non-volatile with a low vapour pressure of $9.3 \times 10^{-11}$ mmHg and therefore inhalation exposure is considered to be negligible for outdoor postapplication activities and a postapplication inhalation exposure assessment was not required.

Calculated dermal MOEs for the postapplication exposure to deltamethrin in agricultural crops exceeded target MOEs and are not of concern. REIs were set at 12 hours for all postapplication activities. The postapplication exposure assessment is outlined in Appendix IV, Table 3.

### 3.2.3 Non-Occupational Exposure and Risk Assessment

Non-occupational risk assessment involves estimating risks to the general population, including youth and children, during or after pesticide application.

The only residential scenario where deltamethrin is registered for use in Canada is the application to turf by commercial applicators. Commercial mixer, loader, and applicator exposure is assessed in Section 3.2.2. As there is no use registered for residential application, there is no potential exposure to homeowners mixing, loading or applying deltamethrin.

**Postapplication Exposure and Risk Assessment**

The USEPA has generated standard default assumptions for developing residential exposure assessments for both applicator and postapplication exposures when chemical- and/or site-specific field data are limited. These assumptions may be used in the absence of, or as a supplement to, chemical- and/or site-specific data and generally result in conservative estimates of exposure. These assumptions, as well as the sentinel populations used to characterize each exposure scenario, are outlined in the Standard Operating Procedure (SOP) for Residential Pesticide Exposure Assessments. The following section from the Residential SOP was used to assess residential postapplication exposure to deltamethrin:

- Section 3: Lawns and Turf

Postapplication exposure refers to an exposure scenario in which an individual is exposed through dermal, inhalation, and/or incidental oral (non-dietary ingestion) routes as a result of being in an environment that has been previously treated with a pesticide.

There is potential for short-term exposure to adults, youth, and children (6 to < 11 years old and 1 to < 2 years old) through contact with transferable residues following commercial applications of deltamethrin to residential turf. Adults, youth, and children have the potential for postapplication dermal exposure; children (1 to < 2 years old) also have the potential for incidental oral exposure.

The following scenarios were assessed for the postapplication exposure assessment for the residential use of products containing deltamethrin:

- Adult, youth, and children (6 to < 11 years old, 1 to < 2 years old) dermal exposure to liquid products applied to lawns and turf.
- Incidental oral (hand-to-mouth, object-to-mouth, and soil ingestion) exposure to children (1 to < 2 years old) from applications to lawns and turf.

As per label directions, deltamethrin can be applied to turf two times per year with a 14 day interval. The postapplication risk assessment was based on these specific conditions of use.

Inhalation exposure is not considered to be a significant route of exposure for people entering a treated area compared to the dermal routes. Deltamethrin is relatively non-volatile with a low vapour pressure of $9.3 \times 10^{-11}$ mmHg, therefore, a postapplication inhalation exposure assessment was not required.

Postapplication dermal exposure was calculated using estimates for foliar residue, leaf-to-skin residue transfer for individuals contacting treated foliage during certain activities, and exposure time. The measure of leaf-to-skin residue transfer for a given crop and activity is known as the TC. TCs are derived from concurrent measurements of exposure and foliar residue and are the ratio of exposure rate (measured in mass of chemical per time (for example, µg/hr)), to residue (measured in mass of chemical per foliar surface area (for example, µg/cm$^2$)). It is the amount of treated surface that a person contacts while performing activities in a given period (usually expressed in units of cm$^2$ per hour) and is specific to a particular population.

For the residential postapplication assessment of deltamethrin, transfer coefficients were derived from the Residential SOPs for activities conducted on turf. Since the individuals monitored in these studies were adults, use of transfer coefficients to assess postapplication exposure for youth, children (6 to < 11 years), and children (1 to < 2 years) were adjusted for body surface area using an adjustment factor of 0.82 (1.59 m$^2$/1.95 m$^2$), 0.55 (1.08 m$^2$/1.95 m$^2$), and 0.27 (0.53 m$^2$/1.95 m$^2$) respectively.

Calculated dermal MOEs for the residential postapplication exposure, golfing and incidental oral exposure to deltamethrin exceeded target MOEs and are not of concern. The residential postapplication risk assessment is outlined in Appendix V, Tables 1-4.

**Dermal Bystander Exposure and Risk Assessment**

There is potential for short-term exposure to deltamethrin for adults, youth, and children (6 to < 11 years old) by entry into treated non-cropland areas (such as hiking through treated forests or parks that have recently been treated).

Calculated MOEs for all populations exceeded target MOEs and are not of concern. Bystander exposure is outlined in Appendix V, Table 5.

### 3.3 Dietary Risk Assessment

In a dietary exposure assessment, the PMRA determines how much of a pesticide residue, including residues in milk and meat, may be ingested with the daily diet.

These dietary assessments are age-specific and incorporate the different eating habits of the population at various stages of life. For example, the assessments take into account differences in children's eating patterns, such as food preferences and the greater consumption of food relative to their body weight when compared to adults. Dietary risk is then determined by the combination of the exposure and the toxicity assessments. High toxicity may not indicate high risk if the exposure is low. Similarly, there may be risk from a pesticide with low toxicity if the exposure is high.

In situations where the need to mitigate dietary exposure has been identified, particular options are considered. Dietary exposure from Canadian agricultural uses can be mitigated through changes in the use pattern. Revisions of the use pattern may include such actions as reducing the application rate or the number of seasonal applications, establishing longer pre-harvest intervals (PHIs), and/or removing uses from the label. In order to quantify the impact of such measures, new residue chemistry studies which reflect the revised use pattern would be required. These data would also be required in order to amend maximum residue limits (MRLs) to the appropriate level. Imported commodities which have been treated also contribute to the dietary exposure and are routinely considered in the risk assessment. The mitigation of dietary exposure that may arise from treated imports is generally achieved through the amendment or establishment of MRLs.

The PMRA considers limiting the use of a pesticide when its risk exceeds 100% of the reference dose. Science Policy Notice SPN2003-03, *Assessing Exposure from Pesticides, A User's Guide*, presents detailed acute and chronic risk assessments procedures.

Residue estimates used in the dietary risk assessment may be conservatively based on the MRLs. They may also be based on the field trial data representing the residues that may remain on food after treatment at the maximum label rate. Surveillance data representative of the national food supply may also be used to derive a more accurate estimate of residues that may remain on food when it is purchased. These include the Canadian Food Inspection Agency's (CFIA) National Chemical Residue Monitoring Program and the United States Department of Agriculture Pesticide Data Program (PDP).

The dietary risk assessment considered exposure from all food and water sources that could potentially contain deltamethrin. Residue estimates for animal commodities were based on anticipated residues calculated on feed residue data, while residue estimates for most plant commodities were mainly based on CFIA pesticide residue monitoring data. Where CFIA monitoring data were not available, PDP monitoring data, field trial data, MRLs or US tolerances were used. Processing factors and food supply information was also used in the assessment where applicable. Refinement for % of crop treated (CT) or probabilistic exposure determination were not used. Exposure to deltamethrin from potentially treated imports is also included in the assessment.

Acute and chronic dietary risk assessments were conducted using the Dietary Exposure Evaluation Model (DEEM-FCID™, Version 2.16) which incorporates food consumption data from the United States Department of Agriculture's Continuing Surveys of Food Intakes by Individuals, 1994–1996 and 1998.

For more information on dietary risk estimates or residue chemistry information used in the dietary assessment, see Appendices VI, VII and VIII.

### 3.3.1 Determination of Acute Reference Dose

**General Population (including pregnant women, infants and children)**

To estimate acute dietary risk (1 day), the acute oral comparative neurotoxicity study in rats was selected for risk assessment. A LOAEL of 1 mg/kg bw was determined in weanlings based on a reduction in acoustic startle response. This LOAEL was selected since it is based on the most sensitive endpoint available in the database, may occur following a single exposure, is derived from a susceptible population (the young) and is protective of other neurological and systemic effects. Data were not sufficient to derive a benchmark dose for this endpoint. Uncertainty factors of 10-fold for interspecies extrapolation and 10-fold for intraspecies variability were used to derive the ARfD. An additional uncertainty factor for lack of a NOAEL was not required since the extent of change (18% decrease) in acoustic startle response was considered to be close to the response threshold. As discussed in the *Pest Control Products Act* Hazard Characterization section, the *Pest Control Products Act* factor has been reduced to 3-fold, resulting in a Composite Assessment Factor (CAF) of 300. The ARfD is calculated according to the following formula:

$$\textbf{ARfD} = \frac{\textbf{LOAEL}}{\textbf{CAF}} = \frac{\textbf{1 mg/kg bw}}{\textbf{300}} = \textbf{0.003 mg/kg bw deltamethrin}$$

This ARfD provides a margin of 2300 to the NOAEL for mortality in pregnant rats due to acute exposure and a margin of 420 to the $\text{BMDL}_{10}$ for decreased motor activity in adult rats.

### 3.3.2 Acute Dietary Exposure and Risk Assessment

Acute dietary risk is calculated considering the highest ingestion of deltamethrin that would be likely on any one day, and using food consumption and food residue values. A statistical analysis compiles all possible combinations of consumption and residue levels to estimate a distribution of the amount of deltamethrin residue that might be consumed in a day. A value representing the high end (95th percentile) of this distribution is compared to the ARfD, which is the dose at which an individual could be exposed on any given day and expect no adverse health effects. When the expected intake of residues is less than the ARfD, then acute dietary exposure is not of concern.

The acute dietary exposure assessment was based on highest residue data from CFIA monitoring program, crop field trials, processing factors, and the assumption that 100% of crops were treated. Where no residue data were available, MRL or US tolerances were used for the exposure determination. The dietary exposure assessment considered all potentially treated food commodities, including imports to Canada. Drinking water contribution to the exposure was accounted for by direct incorporation of the appropriately estimated environmental concentration (EEC), obtained from water modelling (see Section 3.4 below for details), into the dietary exposure evaluation model (DEEM).

The refined acute dietary exposure estimate of deltamethrin from food and water accounted for less than 66% of the ARfD for all population subgroups and is below the level of concern.

### 3.3.3 Determination of Acceptable Daily Intake

**General Population (including pregnant women, infants and children)**

To estimate dietary risk of repeat exposure, the acute oral comparative neurotoxicity study in rats was selected for risk assessment. A LOAEL of 1 mg/kg bw was determined in weanling rats based on reduced acoustic startle response. This LOAEL was selected since it is based on the most sensitive endpoint in the database and neurotoxicity does not increase significantly with increasing duration of exposure. Data were not sufficient to derive a benchmark dose for this endpoint. Uncertainty factors of 10-fold for interspecies extrapolation as well as 10-fold for intraspecies variability were used to derive the ADI. An additional uncertainty factor for lack of a NOAEL was not required since the LOAEL was considered to be close to the response threshold. The *Pest Control Products Act* factor has been reduced to 3-fold as discussed in the *Pest Control Products Act* Hazard Characterization section, resulting in a Composite Assessment Factor (CAF) of 300. The ADI is calculated according to the following formula:

$$\mathbf{ADI = \frac{LOAEL}{CAF} = \frac{1\ mg/kg\ bw/day}{300} = 0.003\ mg/kg\ bw/day\ deltamethrin}$$

This ADI provides a margin of 1830 to the NOAEL for offspring mortality in the reproductive toxicity study and a margin of 1100 to the NOAEL for mortality in pregnant rats due to repeated exposure. This ADI provides a margin of 660 to the NOAEL for reproductive effects in male rats.

### 3.3.4 Chronic Dietary Exposure and Risk Assessment

The chronic dietary risk was calculated by using the average consumption of different foods and the average residue values on those foods. This expected intake of residues was then compared to the ADI. When the expected intake of residues is less than the ADI, then chronic dietary risk is not of concern.

The chronic dietary exposure assessment was based on residue data from CFIA monitoring program, crop field trials, processing factors, and the assumption that 100% of crops were treated. Where no residue data were available, MRL or US tolerances were used for the exposure determination. The dietary exposure assessment considered all potentially treated food commodities, including imports to Canada. Drinking water contribution to the exposure was accounted for by direct incorporation of the appropriate EEC, obtained from water modelling (see Section 3.4 below for details), into the DEEM.

The dietary exposure estimates from food and water ranged from 7 to 29% of the ADI and is not of concern.

### 3.3.5 Cancer Dietary Exposure and Risk Assessment

A cancer risk assessment was not required as no cancer concerns were identified.

## 3.4 Exposure from Drinking Water

### 3.4.1 Concentrations in Drinking Water

Deltamethrin exhibits low solubility in water and has been shown to strongly bind to organic matter and is thus classified as immobile in soil. It is also not overly persistent in soil. Considering these properties, it is not expected that deltamethrin would leach through the soil profile and reach groundwater. Also, given its low solubility, deltamethrin is not likely to dissolve in run-off water. While deltamethrin could enter surface water through the displacement of soil particles in a run-off event, it is expected that deltamethrin bound to organic matter will settle out of the water column into sediment or be removed by flocculation and settling during the water treatment process.

Overall, fate properties of deltamethrin suggest that high amounts of this compound would not be expected in groundwater or surface water.

Given the above considerations, an EEC of 0.2 µg/L was used in the acute and chronic dietary assessments. This level is based on the limit of solubility of deltamethrin in water.

### 3.4.2 Drinking Water Exposure and Risk Assessment

Drinking water exposures were incorporated directly in the acute and chronic dietary exposure assessments. Please refer to Sections 3.3.2 and 3.3.4 for details.

## 3.5 Aggregate Risk Assessment

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal, and inhalation).

### 3.5.1 Toxicology Endpoint Selection for Aggregate Risk Assessment

For oral and inhalation aggregate risk assessment of the general population (including pregnant women, infants and children), for any duration, toxicological endpoints and assessment factors are the same as those for the acceptable daily intake (see section entitled Determination of Acceptable Daily Intake).

Exposure via the dermal route has not been aggregated since no adverse toxicological effects were noted following repeated dermal dosing. It is acknowledged that the repeat-dose dermal study did not measure the most sensitive endpoint for deltamethrin (acoustic startle response) or use a susceptible population (the young). However, following oral administration, there was a small margin between the doses producing a reduced acoustic startle response (1 mg/kg bw) and those producing clinical signs of toxicity (2 mg/kg bw). In view of this, as well as the fact that there were no clinical signs of toxicity observed in the dermal study at a limit dose of 1000 mg/kg bw/day, aggregation of dermal exposure was not necessary.

### 3.5.2 Non-Occupational Aggregate Exposure and Risk Assessment

For deltamethrin, non-occupational aggregation of dermal exposure was not necessary as no adverse toxicological effects were noted following repeated dermal dosing. The only scenario which is expected to co-occur is:

- Incidental oral exposure (hand-to-mouth) and chronic dietary exposure

This aggregation is based on incidental oral (hand-to-mouth) activities for children (1 to <2 years old) from the commercial application of deltamethrin to turf. The target MOE was exceeded for this scenario and is not of concern. The aggregate assessment for deltamethrin is shown in Appendix IX, Table 1.

### 3.6 Biomonitoring Information from the Canadian Health Measures Survey

National data on concentrations of environmental chemicals in Canadians were collected and reported as part of the Canadian Health Measures Survey (CHMS), an ongoing national direct health measures survey (Health Canada, 2013). It was launched in 2007 to collect health and wellness data and biological specimens on a nationally representative sample of Canadians. Biological specimens were analyzed for indicators of health status, chronic and infectious diseases, nutritional status and environmental chemicals.

Pyrethroid pesticides are rapidly metabolized and eliminated from the body through hydrolysis, oxidation, and conjugation. Following oral ingestion, inhalation, or dermal exposure, pyrethroids are metabolized into carboxylic and phenoxybenzoic acids and excreted with urine. Pyrethroids and their metabolites can be measured in blood and urine, and are reflective of recent exposure to the parent compound or the metabolite in the environment. A specific urinary metabolite of deltamethrin was measured in two cycles of CHMS: *cis*-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane-1-carboxylic acid (*cis*-DBCA). In the first cycle, in which individuals were sampled in 2007-2009 and included persons aged 6 to 79 years, the geometric mean (GM) could not be calculated as > 40% of the samples were below the 0.006 µg/L limit of detection (LOD). The 95th percentile was 0.073 µg/L. In the second cycle, in which individuals were sampled in 2009-2011 and included persons aged 3 to 79 years, 37% of the samples were below the LOD. The GM (95% CI) was determined to be 0.012 µg/L, and the 95th percentile was 0.15 µg/L.

The amount of deltamethrin metabolite measured in urine indicates the total amount that has entered the body through all routes of exposure (dermal, inhalation, oral) and from all pathways (diet, residential uses). Exposure for the general population is expected to occur primarily through from dietary sources, an exposure pattern that is best represented by the GM. Residential uses of deltamethrin are likely to result in higher exposures, and consequently higher levels of the metabolites in urine. The 95th percentile reported in CHMS is considered to be more representative of what is assessed in the deterministic aggregate risk assessment than GM (see Section 3.5).

### 3.6.1 Biomonitoring Equivalents

A biomonitoring equivalent (BE) is defined as the concentration or range of concentrations of a chemical or its metabolites in a biological medium (for example, blood, urine etc.) that is consistent with an existing health-based exposure guidance value such as an RfD or ADI. They are intended to be used as screening tools to provide an assessment of whether a chemical biomarker is present at levels well below, near, or at or above concentrations that are consistent with existing risk assessments and exposure guidance values.

BE values were derived for deltamethrin based on the PMRA toxicology review using the method by Aylward (2011). These values were derived based on two biomarkers: deltamethrin (parent) in plasma and *cis*-DBCA in urine (Aylward, 2011). BE values for deltamethrin in plasma were based on extrapolation from measured deltamethrin concentrations in plasma in rats and BE values for DBCA in urine were derived based on pharmacokinetic data from a human volunteer study (adults) on the urinary excretion of deltamethrin and its metabolites. The derived BE value for DBCA in urine was determined to be 19.7 µg/L for all age groups.

The levels of the deltamethrin metabolite as measured in CHMS were much lower than the derived BE for both adults and children, which would indicate this chemical is of low concern (that is, low priority for risk assessment follow-up). This supports the conclusion of the aggregate risk assessment, where the calculated MOEs were above the target MOE and are therefore not of concern.

### 3.7 Cummulative Risk

The Pest Control Products Act requires the Agency to consider the cumulative effects of pest control products that have a common mechanism of toxicity. Deltamethrin belongs to a group of chemicals classified as pyrethroids. Pyrethroids and pyrethrins have a common mechanism of toxicity wherein they all possess the ability to interact with voltage-gated sodium channels ultimately leading to neurotoxicity. Upon completion of the re-evaluation of the individual chemicals in the pyrethroid group, it will be determined whether a cumulative effects assessment is necessary and if so, this will be performed with all relevant chemicals of the common mechanism group.

## 4.0 Impact on the Environment

### 4.1 Fate and Behaviour in the Environment

Deltamethrin enters the terrestrial environment when it is used as an insecticide on a variety of grain, cereal, fruit and vegetable crops as well as on turf, shelterbelts, rangeland, pastures and greenhouses. In the terrestrial environment, deltamethrin is expected to be non-persistent to moderately persistent in aerobic soil ($DT_{50}$ = 6.1-72 days). The majority of deltamethrin is shown to mineralize to $CO_2$; deltamethrin residues are shown to accumulate steadily in soil (17 – 48%) before being further mineralized to $CO_2$. Biotransformation of deltamethrin is expected to be slower in organic soils compared to mineral soils. Only one major transformation product, -(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylic acid ($Br_2CA$), was identified from

laboratory aerobic soil biotransformation studies. Minor transformation products included: α-carbamyl-3-phenoxybenzyl-3- (2,2 - dibromovinyl) – 2,2-dimethylcyclopropanecarboxylate (D-CONH$_2$), α -carboxy-3-phenoxybenzyl cis-2,2-dibromovinyl) – 2,2-dimethylcyclopropanecarboxylate (D-COOH), 3-phenoxybenzoic acid (PBAc), 3-(2-hydroxyphenoxy benzole acid and 3-(4-hydroxyphenoxy) benzoic acid. Phototransformation in soil is not expected to be an important route of transformation.

Deltamethrin has a low vapour pressure ($1.24 \times 10^{-8}$ mm Hg at 25°C) and is not expected to volatilize substantially; however, based on its calculated Henry's constant ($3.1 \times 10^{-2}$ atm.m$^3$/mol at 25°C; $1/H = 7.89 \times 10^{-1}$), deltamethrin has the potential to volatilize from water and moist soil. Although volatility studies indicate that deltamethrin does not readily volatilize from plant and soil surfaces, laboratory and aquatic field data show that volatilization from the surface of water after direct application over water is a significant route of dissipation for deltamethrin. In air, the photochemical oxidative half-life for deltamethrin is estimated to be 16 hours. Based on the criteria set out in the Stolkholm Convention (potential to volatilize and half-life in air greater than 2 days), deltamethrin is unlikely to be susceptible to long range transport.

Deltamethrin is practically immobile in soil due to its strong adsorption onto soil particles and its insolubility in water. However, laboratory adsorption data indicate that the major transformation product Br$_2$Ca is very highly mobile in soil and the minor transformation product PBAc is moderately to highly mobile. When taking into consideration the criteria of Cohen et al (1984[3]) and the groundwater ubiquity score (GUS[4]) it was determined that deltamethrin is unlikely to leach to groundwater. Although deltamethrin has high use and an extensive use pattern, a review of available Canadian and U.S. groundwater monitoring data reveals no detections of deltamethrin. Soil column leaching experiments confirm that deltamethrin residues remain in the upper few inches of soil. In addition, there is no evidence of residue mobility under field conditions. Deltamethrin residues, therefore, are not expected to leach into groundwater.

Deltamethrin can enter the aquatic environment through spray drift and run-off from the application site. Hydrolysis is an important route of transformation under alkaline conditions but is increasingly stable towards neutral and acidic conditions. Phototransformation is not expected to contribute to the dissipation of deltamethrin from the water layer in the photic zone. In aquatic environments, deltamethrin is expected to be non-persistent to moderately persistent (aerobic whole system $DT_{50} = 4 - 141$ days; anaerobic whole system $DT_{50} = 60 - 100$ days), and partition predominantly to sediment. Two major transformation product were identified from laboratory aerobic water/sediment biotransformation studies: Br$_2$Ca and BrCa-isomer 1. Aquatic field studies on the environmental fate of deltamethrin show that deltamethrin is non-persistent in subsurface water with half-lives ranging from 1 hour to 35.7 hours. Aquatic exposure may be signficantly reduced by rapid volatilization of spray applied deltamethrin from the surface microlayer, with initial half-lives measured in minutes (~5 minutes – Muir et al. 1992). As much as 38 - 100% of deltamethrin in the water column may be bound to suspended solids (half-lives for deltamethrin on suspended solids range from 5.7 – 30 hours). Sediments are shown to be an important sink for deltamethrin residues. As a result, exposure to deltamethrin of organisms living in the water column is expected to be short lived.

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[3] Cohen, S.Z., Creeger, S.M., Carsel, R.F., Enfield, C.G. 1984. Potential for pesticide contamination of groundwater resulting from agricultural uses. (PMRA 1573066).

[4] Gustafson, D.I. 1989. Groundwater ubiquity score: a simple method for assessing pesticide leachability. Environmental Toxicology and Chemistry, 8: 339–357. (PMRA 1918524).

The log octanol/water partitioning coefficient for deltamethrin (Kow = 4.6) suggests the potential for bioaccumulation in the food chain. Based on bioconcentation data for freshwater fish (Bioconcentration Factors, BCFs ranging from 144 to 1400, 50% clearance time = 3 to 7 days) and freshwater invertebrates (BCFs = 39 – 305, 50% clearance time = 37 hours), the potential for bioaccumulation is expected to be low.

Environmental fate data for deltamethrin and its transformation products, in the terrestrial and aquatic environment, are summarized in Tables 1 and 2 of Appendix XI, respectively.

## 4.2 Environmental Risk Characterization

The environmental risk assessment integrates the environmental exposure and ecotoxicology information to estimate the potential for adverse effects on non-target species. This integration is achieved by comparing exposure concentrations with concentrations at which adverse effects occur. Estimated environmental exposure concentrations (EECs) are concentrations of pesticide in various environmental media, such as food, water, soil and air. The EECs are estimated using standard models which take into consideration the application rate(s), chemical properties and environmental fate properties, including the dissipation of the pesticide between applications. Ecotoxicology information includes acute and chronic toxicity data for various organisms or groups of organisms from both terrestrial and aquatic habitats including invertebrates, vertebrates, and plants. Toxicity endpoints used in risk assessments may be adjusted to account for potential differences in species sensitivity as well as varying protection goals (protection at the community, population, or individual level).

Initially, a screening level risk assessment is performed to identify pesticides and/or specific uses that do not pose a risk to non-target organisms, and to identify those groups of organisms for which there may be a potential risk. The screening level risk assessment uses simple methods, conservative exposure scenarios (for example, direct application at a maximum cumulative application rate) and sensitive toxicity endpoints. A risk quotient (RQ) is calculated by dividing the exposure estimate by an appropriate toxicity value (RQ = exposure/toxicity), and the risk quotient is then compared to the level of concern (LOC). If the screening level risk quotient is below the level of concern, the risk is considered negligible and no further risk characterization is necessary. If the screening level risk quotient is equal to or greater than the level of concern, then a refined risk assessment is performed to further characterize the risk. A refined assessment takes into consideration more realistic exposure scenarios (such as drift to non-target habitats) and might consider different toxicity endpoints. Refinements may include further characterization of risk based on exposure modelling, monitoring data, results from field or mesocosm studies, and probabilistic risk assessment methods. Refinements to the risk assessment may continue until the risk is adequately characterized or no further refinements are possible.

### 4.2.1 Risks to Terrestrial Organisms

A summary of terrestrial toxicity data for deltamethrin is presented in Appendix XI, Table 3. For the assessment of risk, toxicity endpoints chosen from the most sensitive species were used as surrogates for the wide range of species that can be potentially exposed following treatment with deltamethrin. The terrestrial assessment took into account the range of agricultural application rates that are registered for deltamethrin, taking into consideration that there may be multiple applications of deltamethrin in a use season.

**Terrestrial Invertebrates**

**Earthworms**

The lowest 14-day $LC_{50}$ for *Eisenia foetida is* > 402 mg a.i./kg soil; a chronic 28 day NOEC of $\geq$ 206.5 g a.i./ha is reported based on adult growth, mortality and reproductive performance. The EEC in soil based on the highest ground application rate for shelterbelts (135 g a.i./ha) is 0.06 mg a.i./kg soil; the calculation of the EEC assumes an application made to bare soil with a soil density of 1.5 mg/cm$^3$ and even mixing through a 15 cm depth. The associated risk quotients based on the maximum shelterbelt application rate indicate that deltamethrin is not expected to pose an acute or chronic risk to earthworms (RQ < 1).

**Honey Bees**

Pollinators can be exposed to deltamethrin from contact and/or feeding on contaminated parts of plants, for example, pollen and nectar. In-hive bees, including immature bees, can be exposed via contaminated plant materials brought back by foraging bees. For the Tier I risk assessment for foliar application, the single lowest spray application rate (soybean: 3.25 g a.i./ha) was used to estimate the environmental exposure concentration (EEC).

The tier I risk quotients for acute contact and oral toxicity to honey bee adults exceed the level of concern at the lowest single application rate (RQ = 5.2 and 1.9, respectively).

Higher tier risk assessments were conducted based on a weight of evidence approach. Several semi-field (Tier II) and field (Tier III) studies were conducted on a number of crops using different application rates. No remarkable colony effects were observed. After short term exposure, however, intoxication of individual adult bees did occur on the same day of application. A transient increase in adult bee mortality and a decrease in foraging activity may occur from exposure on the day of spray application. As such, mitigation is proposed to reduce exposure to bees.

**Beneficial arthropods**

The risk to beneficial arthropods from exposure to direct application of deltamethrin was determined based on the most sensitive $LR_{50}$ for the predatory mite *Typhlodromus pyri*, 0.058 g a.i./ha (extended laboratory test). The EECs were determined for both on-field and off-field exposure. The application rates chosen to calculate EECs cover the range of application rates applied with ground boom sprayers (soybean: 3.25 g a.i./ha) and the highest application rate for shelterbelts (135 g a.i./ha).

The deltamethrin EEC values for beneficial predatory and parasitic arthropods were refined to consider foliar interception. The exposure estimates are assuming deposition to a 2-dimensional structure. Therefore, the values can be corrected to take into account the 3-dimensional structure where a certain fraction is intercepted by the crop (for in-field exposure) or the off-field vegetation (for off-field exposure). For the in-field EEC, crop-specific foliar interception factors are applied to the application rate. For the off-field EEC, a vegetation distribution factor is applied to the application drift rate.

The risk quotients exceed the LOC for predatory arthropods on field at all application rates (RQ = 45 – 1862) and off-field at the highest application rate for shelterbelts (RQ = 26). Spray drift of deltamethrin may pose a risk to beneficial arthropods at single application rates higher than 5.4 g a.i./ha.; this value was derived by back calculation (i.e. soybean application rate = 3.25 g a.i./ha divided by the off-field risk quotient = 0.6).

In higher tier studies (field), significant reductions in population abundance of several arthropod species were observed; while some species recovered shortly after treatments within the registered application rate range (12.5 g a.i./ha), others were unable to recover within the same growing season. Consequently, precautionary label statements are proposed to inform users of the potential risks to beneficial insects.

**Terrestrial Plants**

Non-target plants could be exposed to deltamethrin by overspray and spray drift. The risk to non-target plants was assessed based on an $EC_{25}$ of > 12.5 g a.i./ha based on seedling emergence and vegetative vigor limit tests conducted with both monocot (3) and dicot (5) crop species. No significant adverse effects were observed for any of the endpoints measured (seedling emergence, plant survival, plant dry weight, phytotoxicity) as compared to the controls for any of the crops tested. At the maximum single seasonal rate of 135 g a.i/ha (shelterbelt use), the screening level risk quotient ($EEC/EC_{25} < 10.8$) exceed the level of concern.

EECs for deltamethrin resulting from spray drift were estimated based on the maximum percentage rate (% spray drift) that will drift from the application site during spraying onto areas 1 m downwind from the edge of the spray swath. The risk associated with spray drift off the treated field was assessed, taking into consideration spray drift spray quality of ASAE fine for ground and aerial application (11 and 26%, respectively) and ASAE fine for airblast application (74%), 1 m downwind from the site of application. EECs were determined for the maximum cumulative seasonal rate for ground, airblast and aerial agricultural uses and the maximum single rate for ground application to shelterbelts; cumulative application rates were calculated based on the 90th centile confidence bound on the mean of aerobic soil half-life values adjusted to 25°C (58 days).

The results of the spray drift assessment indicate that airblast applications (RQ <2.1) may pose a risk to terrestrial plants. Given that the mode of action (nervous system, in other word, disruption of action potential in neurons) does not apply to plants, adverse effects to terrestrial vascular plants are not anticipated. Moreover, the collective results of laboratory and outdoor aquatic mesocosm studies demonstrate no adverse effects to phytoplankton or aquatic macrophyte species. Deltamethrin is registered for pest control on a variety of plant species at a wide range of application rates. No incidents have been reported in the U.S. or Canada that indicate that deltamethrin use causes adverse effects to terrestrial vascular plants. Based on the weight of evidence, deltamethrin is not expected to pose a risk to terrestrial plants.

**Terrestrial vertebrates**

For the bird and mammal risk assessment, the ingestion of food items contaminated by spray droplets is considered to be the main route of exposure. The risk assessment is thus based on the estimated daily exposure which takes into account the expected concentration of deltamethrin on various food items immediately after the last application and the food ingestion rate of different sizes of birds and mammals. At the screening level, only the most conservative exposure estimates are used - i.e. the cumulative application rate for agricultural uses that results in the highest estimated daily exposures (peppers, field corn - three applications of 15 g a.i./L with a 5 day interval) as well as the maximum single seasonal application rate for shelterbelts (135 g a.i./ha).

For birds, the level of concern (LOC) is not exceeded at the screening level for acute and reproductive effects. Deltamethrin, therefore, is not expected to pose an acute or reproductive risk to birds.

For mammals, screening level risk quotients exceed the level of concern on an acute basis (all sizes of mammals) and on a reproductive basis (larger sizes only) when considering the shelterbelt use (Table 4, Appendix XI). When considering uses on peppers and field corn, screening level risk quotients exceed the level of concern for 35g mammals (Table 5, Appendix XI).

To further characterize the risk to mammals, the assessment was expanded to include a range of deltamethrin residue concentrations on all relevant food items. The risk associated with the consumption of food items contaminated from spray drift off the treated field was also assessed taking into consideration the projected spray deposition at 1 m downwind from the site of application (11% for ground applications with a spray quality of ASAE fine). Refined risk quotients only exceed the level of concern on an acute basis for 35 g mammals feeding on-field on short grass and forage crops (RQ = 1.45 and 1.25, respectively) ( Table 6, Appendix XI).

Although small wild mammals frequent shelterbelts for cover and refuge, the risk assessment shows that adverse effects would only occur at the highest residue level. The overall risk to mammals, however, is considered to be low for the following reasons: 1) only 1 application is made to shelterbelts per season; 2) minimal risk is identified in the risk assessment using mean residue values and 3) only two food items are identified as a feeding risk with the level of concern only slightly exceeded; it is unlikely that these food items would comprise 100% of the diet of small mammals. Although the risk to small mammals is considered to be low, a label statement is proposed to inform the user of the potential hazard.

### 4.2.2 Risks to Aquatic Organisms

A summary of aquatic toxicity data for deltamethrin is presented in Table 7 (Appendix XI).

**Screening Level Assessment**

The initial conservative screening level assessment considered the cumulative application rate for agricultural uses that results in the highest EEC for aquatic systems (Broccoli, etc. - 10 g a.i./ha × 8 at 10 d intervals) and the highest application rate used on shelterbelts (135 g a.i./ha) based on direct application to water bodies with a depth of 15 cm (seasonal water body for amphibian endpoints) and 80 cm (permanent water body for remaining endpoints). The aquatic EEC for the highest cumulative application rate was conservatively estimated by adjusting the sum of the applications for dissipation between applications using a $DT_{50}$ in water of 118.5 days. This value is the 80th percentile of whole system $DT_{50}$ values from acceptable aerobic aquatic biotransformation studies.

For the assessment of risk, toxicity endpoints chosen from the most sensitive species tested were used as surrogates for the wide range of species that can be potentially exposed following treatment with deltamethrin. The acute endpoints were derived by dividing the $EC_{50}$ or $LC_{50}$ from the appropriate laboratory study by a factor of two (2) for aquatic invertebrates, and by a factor of 10 for fish and amphibians. In order to assess the risk to amphibians for a chronic exposure to deltamethrin, the endpoint value for the most sensitive fish was used as surrogate data.

Toxicity endpoints for most aquatic species were several orders of magnitude lower than the screening level EECs with the exception of those for freshwater algae. The risk quotients greatly exceed the level of concern (RQ = 173 - 113000) for acute and chronic effects for all aquatic species with the exception of freshwater algae.

**Refined Risk Assessment for Aquatic Organisms**

Given the conservative assumption made in the screening level assessment (direct application to a water body), a refined assessment was conducted to better characterize the risk to aquatic organisms. Sufficient acute toxicity data was available for freshwater and estuarine marine invertebrates and freshwater fish to determine $HC_5$s (the 5th percentile of the species sensitivity distribution (SSD) for the $LC_{50}$ at 50% confidence intervals). A species sensitivity distribution (SSD) was determined for non-target freshwater and marine invertebrates and freshwater fish based on the available data for 32, 7 and 23 species, respectively. The $HC_5$ is the concentration which is theoretically protective for 95% of species. At the $HC_5$ exposure level, five percent of all species will be exposed to a concentration which exceeds their $LC_{50}$ toxicity value. The acute $HC_5$ values for freshwater invertebrates, estuarine/marine invertebrates and freshwater fish are $3.6 \times 10^{-5}$, $1.21 \times 10^{-4}$ and 0.22 µg a.i./L, respectively.

**Spray drift refinement**

The risk to aquatic organisms was further characterized by taking into consideration the concentrations of deltamethrin that could be deposited in off-field aquatic habitats that are downwind and directly adjacent to the treated field through spray drift. Review of the labels for deltamethrin-containing end-use products indicate that the end-use products are applied by a variety of application methods. The maximum amount of spray that is expected to drift 1m downwind from the application site during spraying using field sprayer and aerial application methods is determined based on a fine spray droplet size: field sprayer = 11%, aerial = 26%. The maximum amount of spray that is expected to drift 1m downwind from the application site during spraying using airblast application is 74% and 59% for early and late application, respectively. Given the variation in percent drift off site for each of the application methods, the potential risk from drift was assessed for the minimum single ground application for soybean (3.25 g a.i./ha) and the maximum single ground application rate for shelterbelts; these application rates cover the full range of application rates and application methods.

Laboratory and aquatic field data show that volatilization from the surface of water after direct application over water is a significant route of dissipation for deltamethrin. The aquatic drift exposure scenario, which assumes instantaneous and complete mixing of deltamethrin within the water body, therefore, can be viewed as conservative.

The risk to aquatic organisms resulting from spray drift is summarized in Table 8 (Appendix XII). The risk quotients indicate that the LOC is exceeded for all organisms and all application methods on an acute basis (RQs = 2.6 to 15500), with the exception of freshwater and estuarine/marine fish at the lowest field sprayer single application rate (RQ = 0.2 and 0.8, respectively). However, spray drift of deltamethrin may pose a risk to freshwater and marine/estuarine fish at single application rates higher than 16.3 and 4.1 g a.i./ha, respectively (calculated by back calculation using the single lowest crop application rate – 3.25 g a.i./ha by fish RQ). On a chronic basis, the RQs indicate that the LOC is exceeded for all organisms and all application methods (RQ = 1.3 – 719).

**Aquatic field studies**

Based on laboratory toxicity data for single species, the aquatic risk assessment shows aquatic invertebrates to be at most risk from deltamethrin exposure. Higher tier studies confirm that the most sensitive aquatic organisms are invertebrates. Studies of ecological effects of deltamethrin in a variety of freshwater pond systems consistently show that certain components of the invertebrate community are particularly at risk. Collectively, the mesocosm results indicate that certain zooplankton and insect taxa (for example, cladocera – *Daphnia* species, Chaoborus; insect larvae - chironomid, ephemeroptera, anisoptera species; fairy shrimps) are more sensitive to deltamethrin exposure than other invertebrate taxa (for example, rotifers, copepods, odonata and non-arthropods – gastropods, nematode, oligochaetes). Recovery rates reported for invertebrate populations following deltamethrin application to ponds are variable ranging from a few days for some taxa and up to several weeks for others. In some cases the effects on certain species were demonstrated to be dependent on their location within the ponds (sediment, water column or associated with macrophytes). Of the several mesocosm studies reviewed, only two used a suitable dose-response study design capable of providing NOEC values. NOEC values for various invertebrate species populations ranged from 1 ng a.i./L to ≥ 180 ng a.i./L, depending on the taxa or species; the lowest community level NOEC reported was 18 ng a.i./L (based on taxonomic richness, which will be used to determine buffer zones for freshwater aquatic habitats.

**Runoff Refinement**

Aquatic organisms can also be exposed to deltamethrin from foliar applications as a result of runoff into a body of water. The linked models PRZM (Pesticide Root Zone Model) and EXAMS (Exposure Analysis Modeling System) were used to predict estimated environmental concentrations (EECs) resulting from runoff of deltamethrin following application. The models were run at the lowest single rate (to assess risk at the lowest possible use rate) and the highest cumulative rate (to cap the highest risk possible) for each of the application methods: the lowest single application rate is for use on soybean at 5.25 g ai/ha (ground) and the highest seasonal application rate for use on broccoli (8 × 10 g a.i./ha @ 10d, ground), apples (3 × 12.5 g a.i./ha @ 7d, airblast), and corn (1 × 15 g a.i./ha, aerial). The deltamethrin EECs in a 1-ha receiving water body (80 and 15 cm deep) predicted by PRZM-EXAMS at the lowest and highest application rate are presented in Table 9 of Appendix XI. The values reported by PRZM/EXAMS are 90$^{th}$ percentile concentrations of the concentrations determined at a number of time-frames including the yearly peak, 96-hr, 21-d, 60-d, 90-d and yearly average.

Acute and chronic RQ values were calculated using an EEC for the time frame which most closely matched the exposure time used to generate the endpoint (for example, a 96 hour $LC_{50}$ would use the 96 hour value generated by the model; a 21 day NOEC would use the 21 day EEC value). The acute $HC_5$ values for invertebrates (freshwater and marine) and for freshwater fish are based on data with 48 and 96 hour exposure periods, respectively.

The refined risk assessment to aquatic organisms from deltamethrin runoff is summarized in Table 10 (Appendix XI). The RQs derived for acute exposure exceed the LOC in freshwater and marine invertebrates at all deltamethrin application rates (RQ = 1.4 – 55 – freshwater, RQ = 42 – 1583 – marine). For amphibians, the RQ exceeds the LOC for acute effects at the highest ground crop application rate only (broccoli, RQ = 1.6).

The RQs derived for chronic exposure indicate that the LOC is not exceeded for all aquatic organisms except for freshwater invertebrates (RQ = 2.9) and amphibians (RQ = 1.3) at the highest ground application rate only. For freshwater aquatic communities, the LOC is exceeded for the highest ground and aerial applications (broccoli RQ = 11 and corn RQ = 5.2, respectively; these RQ values are based on peak EECs).

Although deltamethrin has an extensive use pattern, it is very uncommon for it to be found in water, largely as a result of its very low persistence and solubility in water. A review of available Canadian surface water monitoring data (samples collected from 1981 to 2007), reveals no detections of deltamethrin in Canada and only two detections (0.8 % detection frequency) of deltamethrin from the US data searched (both of which occurred in Californian surface water); both detections were quite low, 0.004 µg/L (2006) and 0.231 µg/L (2008).

An assessment of the potential risk to aquatic organisms using EEC's based on surface water monitoring data, therefore, could not be conducted. Based on the limited detections and the environmental fate of this chemical it is expected that the potential exposure of aquatic organisms to deltamethrin will be limited.

# 5.0 Value

Deltamethrin has been registered in Canada since 1985 for use on food and non-food crop sites. Deltamethrin is a broad spectrum insecticide that is currently registered on field, greenhouse and orchard crops, ornamentals and turf to control numerous insects. These include many species of weevils, cutworms, flea beetles, moths, aphids, tent caterpillars, coneworms, leafrollers, leafhoppers, midges, webworms, corn borers and corn earworms. Deltamethrin also controls cutworms and grasshoppers in cereal crops, flax, lentils and tobacco and grasshopper in pastures, rangelands and roadsides. Deltamethrin is also applied in shelterbelts for the control of willow sawfly, blister beetle, grey willow leaf beetle, caragana aphid, Eastern spruce budworm, spruce coneworm, spring spruce needle moth, spotted poplar aphid, prairie tent caterpillar and forest tent caterpillar.

Deltamethrin contributes to resistance management strategy by helping to delay the development of resistance when used in rotation with other insecticides with different modes of action.

# 6.0 Pest Control Product Policy Considerations

## 6.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy: persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, deltamethrin and its transformation products were assessed in accordance with the PMRA Regulatory Directive DIR99-03[7] and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

- Deltamethrin does not meet all Track 1 criteria, and is not considered a Track 1 substance. See Table 11 of Appendix XI for comparison with Track 1 criteria.

- Deltamethrin does not does not form any transformation products that meet all Track 1 criteria.

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[7] DIR99-03, *The Pest Management Regulatory Agency's Strategy for Implementing the Toxic Substances Management Policy*.

The use of deltamethrin is not expected to result in the entry of TSMP Track-1 substances into the environment.

### 6.2 Formulants and Contaminants of Health or Environmental Concern

During the review process, contaminants in the technical and formulants and contaminants in the end-use products are compared against the *List of Pest control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*[6].

The list is used as described in the PMRA Notice of Intent NOI2005-01[7] and is based on existing policies and regulations including: DIR99-03; and DIR2006-02[8], and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusions:

- Based on the manufacturing process used, impurities of human health or environmental concern as identified in the Canada Gazette, Part II, Vol. 142, No. 13, SI/2008-67 (2008-06-25), including TSMP Track 1 substances, are not expected to be present in the deltamethrin products.
- Deltamethrin end-use products do not contain any formulants or contaminants of health or environmental concern identified in the *Canada Gazette*.

## 7.0 Incident Reports

Since April 26, 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to the PMRA within a set time frame. Incidents are classified into six major categories including effects on humans, effects on domestic animals and packaging failure. Incidents are further classified by severity, in the case of humans for instance, from minor effects such as skin rash, headache, etc., to major effects such as reproductive or developmental effects, life-threatening conditions or death.

The PMRA will examine incident reports and, where there are reasonable grounds to suggest that the health and environmental risks of the pesticide are no longer acceptable, appropriate measures will be taken, ranging from minor label changes to discontinuation of the product.

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[6] *Canada Gazette*, Part II, Volume 139, Number 24, SI/2005-114 (2005-11-30) pages 2641–2643: *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* and in the order amending this list in the *Canada Gazette*, Part II, Volume 142, Number 13, SI/2008-67 (2008-06-25) pages 1611-1613. *Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

[7] NOI2005-01, *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* under the New Pest Control Products Act.

[8] DIR2006-02, *PMRA Formulants Policy.*

### 7.1 Human and Animal Incident Reports

As of February 12th 2014, there were 11 human and 28 domestic animal incident reports submitted to the PMRA for products containing deltamethrin. The symptoms reported in four human incidents were determined to have some degree of association with the reported exposure. One incident was classified as major and occurred in the United States. The individual in this report described exposure following re-entry into a home treated with a deltamethrin product. Symptoms described in the report included effects like anorexia, headache, muscle spasms, and muscle weakness. In the three other incidents, all of which were minor, exposure was reported to have occurred during application activities (two cases) or when handling a deltamethrin product in a retail store (one case). Skin irritation effects were reported in all of these cases.

Most domestic animal incidents involving deltamethrin occurred in the United States (26 reports). There was some degree of association between the symptoms and the reported exposure in the case of 16 incidents. Exposure occurred as a result of suspected contact with a treated area, either inside or outside the home, following application of the product. The symptoms reported in animals included gastrointestinal effects like vomiting and nervous and muscular effects like ataxia and convulsions (PMRA, 2014).

The USEPA identified 118 case reports attributable to exposure to deltamethrin in the OPP Incident Data System (IDS) between 2002 and 2008. Among the case reports, gastrointestinal, dermal, upper respiratory, neurological, ocular, cardiovascular and combination symptoms were reported. The majority of the reported symptoms involved upper respiratory and dermal effects. Upper respiratory effects included shortness of breath, asthma, respiratory distress, respiratory irritation, coughing/choking, difficulty breathing, sinus problems, chest congestion and pain, and a combination of effects. Most of the incidents were not severe; however patients could exhibit multiple symptoms.

The USEPA also identified 65 case reports in the NIOSH SENSOR database which involved exposures to deltamethrin alone. There were no fatalities; 58 of the cases were classified as low severity and 7 were classified as moderate severity. Eighteen of the cases involved minors less than 18 years of age. The most prevalent health effects were gastrointestinal, neurological, respiratory, dermal and ocular as well as a combination of effects. Of the 65 cases, 12 cases were exposed by drift, 15 cases were occupational exposures, 8 cases resulted from homeowner misuse, 18 cases did not result from homeowner misuse, 5 cases involved ingestion and 7 cases were "unknown".

The California Department of Pesticide Regulation reported 8 cases of possible or probable exposures to deltamethrin alone between 1996 and 2007. Symptoms resulted from accidental exposure or were observed following re-entry into treated areas and included nausea, dizziness, headache, difficulty breathing, tingling sensations of the skin, skin redness, dermal itching and burning sensations, tremors, nasal congestion, sore throat, chest pain, cough, skin redness, jaw tightening, lacrimation, disorientation and rapid heart rate.

Surveillance of workers identified painful pruritis in some individuals exposed by direct dermal contact to deltamethrin followed by erythema and desquamation. Paresthesia of the legs, mouth and tongue, diarrhea, severe headache, dizziness, fatigue, nausea, transient changes in electroencephalogram, muscular twitching and convulsions were also reported in occupationally-exposed workers. The severity of these effects was related to duration and frequency of exposure to deltamethrin.

While causality has not been established for the effects noted in the incident reports, many symptoms in humans are consistent with over-exposure to deltamethrin. These incident reports were considered in this evaluation and did not affect the risk assessment.

### 7.2 Environmental Incident Reports

As of October 1, 2013, there was one environmental incident reported to the PMRA involving the active ingredient deltamethrin. This incident occurred when the water used to douse a fire in a chemical storage facility overflowed into a nearby stream and resulted in fish mortality. There were other chemicals involved and it was considered unlikely that the active ingredient deltamethrin was associated with the reported fish mortality.

There is only one incident reported in the Ecological Incident Information System in the United States. The incident involved the death of 350 bullhead fish in a golf course pond after misuse of three pesticides (deltamethrin, thiophanate-methyl and imidacloprid). Based on measured concentrations in pond water (0.13 µg deltamethrin/L), deltamethrin was considered to be the probable cause of the fish kill.

## 8.0 Organisation for Economic Co-operation and Development Status of Deltamethrin

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum in which governments can work together to share experiences and seek solutions to common problems.

As part of the re-evaluation of an active ingredient, the PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries. In particular, decisions by an OECD member to prohibit all uses of an active ingredient for health or environmental reasons are considered for relevance to the Canadian situation.

Deltamethrin is currently acceptable for use in other OECD member countries, including the United States, Australia, and the European Union. As of 9 April 2015, no decision by an OECD member country to prohibit all uses of deltamethrin for health or environmental reasons has been identified.

# 9.0 Proposed Re-Evaluation Decision

## 9.1 Proposed Regulatory Actions

### 9.1.1 Proposed Regulatory Action Related to Human Health

The PMRA has determined that the dietary and drinking water risks, worker risks during mixing, loading and application, and residential usage risks are acceptable for all uses provided that the proposed mitigation measures are implemented. Mitigation label statements related to toxicology and occupational handling are listed in Appendix XIII.

### 9.1.2 Proposed Regulatory Action Related to Environment

To reduce the effects of deltamethrin in the environment, mitigation in the form of precautionary label statements and spray buffer zones are proposed. Information that could facilitate buffer zone refinement may be submitted during the consultation period. The PMRA is in the process of revising its approach to buffer zones for all chemicals and will consult broadly on the revised approach prior to implementation. The buffer zone requirements proposed in this document are based on the PMRAs current approach. Buffer zones identified in this proposed decision document may be revised based on any new information received and on any future revisions to the Agency's approach to calculating buffer zones. Environmental mitigation label statements are listed in Appendix XIII.

## List of Abbreviations

| | |
|---|---|
| ADI | Acceptable Daily Intake |
| a.i. | Active Ingredient |
| ARfD | Acute Reference Doseatm Atmosphere |
| ATPD | Area Treated Per Day |
| BAF | Bioaccumulation Factor |
| BCF | Bioconcentration Factor |
| BE | Biomonitoring Equivalent |
| bw | Bodyweight |
| CAF | Composite Assessment Factor |
| CAS | Chemical Abstracts Service |
| CFIA | Canadian Food Inspection Agency |
| CHMS | Canadian Health Measures Survey |
| cm | Centimetre(s) |
| $cm^2$ | Centimeter(s) Squared |
| CT | Crop Treated |
| DEEM | Dietary Exposure Evaluation Model |
| DFOP | Double First Order in Parallel |
| DFR | Dislodgeable Foliar Residue |
| $DT_{50}$ | Dissipation Time 50% (the time required to observe a 50% decline in concentration) |
| $DT_{90}$ | Dissipation Time 90% (the time required to observe a 90% decline in concentration) |
| dw | Dry Weight |
| $EC_{25}$ | Effective Concentration on 25% of the population |
| EDE | Estimated Daily Exposure |
| EEC | Estimated Environmental Exposure Concentration |
| FC | Food Consumption |
| FHE | Food Handling Establishment |
| FIR | Food Ingestion Rate |
| g | Gram(s) |
| GB | Groundboom |
| GM | Geometric Mean |
| ha | Hectare |
| HPLC | High Performance Liquid Chromatography |
| HtM | Hand-to-Mouth |
| IUPAC | International Union of Pure and Applied Chemistry |
| kg | Kilogram |
| $K_d$ | Soil-Water Partition Coefficient |
| $K_F$ | Freundlich Adsorption Coefficient |
| $K_{oc}$ | Organic-Carbon Partition Coefficient |
| Kow | n-Octanol/water partition coefficient at 25°C |
| L | Litre(s) |
| $LC_{50}$ | Lethal Concentration 50% |
| $LD_{50}$ | Lethal dose 50% |
| 1/n | Exponent for the Freundlich Isotherm |

| | |
|---|---|
| LOAEL | Lowest Observed Adverse Effect Level |
| LOD | Limit of Detection |
| LOEC | Lowest observed effect Concentration |
| LOQ | Limit of Quantitation |
| mg | Milligram(s) |
| mL | Millilitre(s) |
| M/L/A | Mixer/Loader/Applicator |
| $m^2$ | Meters Squared |
| Max | Maximum |
| mg | Milligram(s) |
| mmHg | Millimeter(s) of Mercury |
| MoA | Mode of Action |
| MOE | Margin of Exposure |
| mPa | Millipascal(s) |
| MPGH | Mechanically Pressurized Handgun |
| MPHG | Manually Pressurized Handwand |
| MRID | US EPA's Master Record Identifier Number |
| MRL | Maximum Residue Limit |
| MS | Mass Spectrometry |
| n/a | Not Available |
| nm | Nanometre(s) |
| NOAEL | No Observed Adverse Effect Level |
| NOEC | No Observed Effect Concentration |
| NOEL | No Observed Effect Level |
| N/R | Not Required |
| OC | Organic Carbon Content |
| OM | Organic matter Content |
| OtM | Object-to-Mouth |
| PF | Protection Factor |
| PHED | Pesticide Handlers Exposure Database |
| PHI | Pre-harvest Interval |
| p*K*a | Dissociation Constant |
| PMRA | Pest Management Regulatory Agency |
| PND | Post Natal Day |
| PPE | Personal Protection Equipment |
| ppm | Parts Per Million |
| REI | Restricted-entry Interval |
| RfD | Reference Dose |
| ROW | Right-of-Way |
| RSD | Relative Standard Deviation |
| SFO | Single First Order |
| SO | Solid |
| SOP | Standard Operating Procedure |
| SRt | Soil Residue (on Day 't') |
| SU | Suspension |
| $t_{1/2}$ | Half-life |
| TC | Transfer Coefficient(s) |
| TRR | Total Radioactive Residue |

| | |
|---|---|
| TSMP | Toxic Substances Management Policy |
| TTR | Turf Transferable Residue(s) |
| USEPA | United States Environmental Protection Agency |
| UV | Ultraviolet |
| v/v | Volume per Volume Dilution |
| μg | Microgram(s) |
| μL | Microlitre(s) |

## Appendix I Registered deltamethrin products as of March 2015[1]

| Registration Number | Marketing Class | Registrant | Product Name | Formulation Type | Guarantee |
|---|---|---|---|---|---|
| 18092 | Technical | Bayer CropScience Inc. | Deltamethrin Technical Insecticide | solid | deltamethrin 99.5% |
| 17734 | Commercial | Bayer CropScience Inc. | Decis 5 EC Insecticide (Prairies and Peace River Region of BC) | Emulsifiable Concentrate | deltamethrin 50 g/L |
| 20078 | Commercial | Bayer CropScience Inc. | Decis Flowable Insecticide (Prairies and Peace River Region of BC) | Suspension | deltamethrin 50 g/L |
| 22478 | Commercial | Bayer CropScience Inc. | Decis 5 EC Insecticide (Eastern Canada and British Columbia) | Emulsifiable Concentrate | deltamethrin 50 g/L |
| 25573 | Commercial | Bayer CropScience Inc. | Decis Flowable Insecticide (Eastern Canada and British Columbia) | Suspension | deltamethrin 50 g/L |
| 28791 | Commercial | Bayer CropScience Inc. | Deltagard SC Insecticide | Suspension | deltamethrin 50 g/L |
| 29611 | Commercial | Bayer CropScience Inc. | Concept Liquid Insecticide | Suspension | imidacloprid 75 g/L<br>deltamethrin 10 g/L |

[1] excluding discontinued products or products with a submission for discontinuation

## Appendix II Registered commercial class uses of deltamethrin in Canada as of January 18, 2013.

| Sites | Pests | Formulation Type[1] | Application Methods and Equipment | Application Rate (g a.i./ha) |  | Maximum Number of Applications per Year | Typical Number of Days Between Applications | Supported Use[2] |
|---|---|---|---|---|---|---|---|---|
|  |  |  |  | Maximum Single | Maximum Cumulative |  |  |  |
| Use-site Category # 13: Terrestrial Feed Crops |  |  |  |  |  |  |  |  |
| Alfalfa seed production only | Alfalfa weevil, lygus bug | EC | Ground | 12.5 | 12.5 | 1 | Not applicable | Y |
|  |  | SC |  |  |  |  |  |  |
| Established red clover for seed production only | Lesser clover leaf weevil | EC | Ground | 12.5 | 25 | 2 | 14 | Y, M |
| Pastures / Rangeland | Grasshoppers | EC | Ground | 7.5 | 22.5 | 3 | 5 | Y, M |
|  |  |  | Aerial | 7.5 | 15 | 2 | 5 |  |
|  |  | SC | Aerial | 6 | 12 | 2 | 5 | Y |
|  |  |  |  | 7.5 | 15 | 2 | 5 | Y, M |
| Use-site Category #13 & 14: Terrestrial Feed Crops and Terrestrial Food Crops |  |  |  |  |  |  |  |  |
| Apples | Apple aphid<br>Apple brown bug<br>Mullein plant bug<br>Eye spotted budmoth<br>Fruit tree leafroller<br>Oblique banded leafroller<br>Pale apple leafroller<br>White apple leafhopper | EC | Ground | 10 | 30 | 3 | 7 | Y |
|  | Winter moth |  |  | 7.5 | 22.5 |  |  |  |
|  | Apple leaf curling midge<br>Tentiform leaf miner (adults only) |  |  | 12.5 | 37.5 | 3 | 7 |  |
|  | Codling moth |  |  |  |  |  | 10 |  |
|  | Oriental fruit moth |  |  |  |  |  | 12 | Y, M |
|  | Apple aphid<br>Apple brown bug<br>Mullein plant bug<br>Eye spotted budmoth<br>Fruit tree leafroller<br>Oblique banded leafroller<br>Pale apple leafroller<br>White apple leafhopper | SC | Ground | 10 | 30 | 3 | 7 | Y |
|  | Winter moth |  |  | 7.5 | 22.5 |  |  |  |
|  | Apple leaf curling midge<br>Tentiform leaf miner (adults only) |  |  | 12.5 | 37.5 |  |  |  |

| Site | Pests | Formulation Type¹ | Application Methods and Equipment | Application Rate (g a.i./ha) |  | Maximum Number of Applications per Year | Typical Number of Days Between Applications | Supported Use²³ |
|---|---|---|---|---|---|---|---|---|
|  |  |  |  | Maximum Single | Maximum Cumulative |  |  |  |
|  | Codling moth |  |  |  |  |  | 10 |  |
| Barley | Cutworm | EC | Ground and aerial | 10 | 10 | 1 | Not applicable | Y |
|  |  | SC |  |  |  |  |  |  |
|  | Grasshopper | EC | Ground and aerial | 7.5 | 22.5 | 3 | 7 | Y |
|  |  | SC |  |  | 15 | 2 |  |  |
| Corn, field | European corn borer | EC | Ground | 15 | 45 | 3 | 7 | Y |
|  | Western bean cutworm |  |  |  |  |  |  | Y, W |
|  | European corn borer | SC |  |  |  |  |  | Y |
| Corn, sweet | Western bean cutworm | EC | Ground | 15 | 30 | 3 | 7 | Y, W |
|  | European corn borer<br>Corn earworm |  |  |  |  |  |  | Y |
|  | Western bean cutworm |  | Aerial | 15 | 15 | 1 | Not applicable | Y, W |
|  | European corn borer<br>Corn earworm |  |  |  |  |  |  | Y |
|  | European corn borer<br>Corn earworm | SC | Ground | 15 | 30 | 2 | 7 | Y |
|  |  |  | Aerial | 15 | 15 | 1 | Not applicable |  |
| Corn, sweet (high organic or muck soils) | European corn borer<br>Corn earworm | EC | Ground and aerial | 10 | 10 | 1 | Not applicable | Y |
|  |  | SC |  |  |  |  |  |  |
| Flax | Cutworm | EC | Ground and aerial | 10 | 10 | 1 | Not applicable | Y |
|  |  | SC |  |  |  |  |  |  |
|  | Clover cutworm | EC |  | 7.5 | 7.5 | 1 |  |  |
|  | Beet webworm |  | Ground |  |  |  |  |  |
|  | Grasshopper |  | Ground | 7.5 | 22.5 | 3 | 7 | Y |
|  |  |  | Aerial |  | 15 | 2 |  |  |
|  |  | SC | Ground | 7.5 | 22.5 | 3 | 7 | Y |
|  |  |  | Aerial |  | 15 | 2 |  |  |
| Oats | Cutworm | EC | Ground and aerial | 10 | 10 | 1 | Not applicable | Y |
|  |  | SC |  |  |  |  |  |  |
|  | Grasshopper | EC | Ground and aerial | 7.5 | 22.5 | 3 | 7 |  |
|  |  | SC |  |  | 15 | 2 |  |  |
| Potatoes | Colorado potato beetle<br>Tarnished Plant Bug<br>Leafhopper<br>Potato Flea Beetle | EC and SC | Ground | 7.5 | 22.5 | 3 | 5 | Y |
|  | Tuber Flea Beetle |  |  | 10 | 30 | 3 | 5 |  |
|  | Potato aphid<br>Buckthorn Aphid |  |  | 12.5 | 25 | 2 | 5 |  |
|  | European corn borer | EC |  | 12.5 | 25 | 2 | 5 |  |
|  |  | SC | Ground and aerial | 6.5 | 19.5 | 3 | 5 |  |

| Sites | Pests | Formulation Type[1] | Application Methods and Equipment | Application Rate (g a.i./ha) | | Maximum Number of Applications per Year | Typical Number of Days Between Applications | Supported Use?[2] |
|---|---|---|---|---|---|---|---|---|
| | | | | Maximum Single | Maximum Cumulative | | | |
| | Colorado potato beetle<br>Tarnished Plant Bug<br>Leafhopper<br>Potato Flea Beetle | EC | Aerial | 7.5 | 15 | 2 | 3 | |
| | Aphids<br>Colorado potato beetle<br>Tarnished Plant Bug<br>Leafhopper<br>Potato Flea Beetle | SU | Ground and Aerial | 6.5 | 19.5 | 3 | 5 | |
| Potatoes (high organic or muck soils) | Colorado potato beetle<br>Tarnished Plant Bug<br>Leafhopper<br>Potato Flea Beetle | EC and SU | Ground and aerial | 7.5 | 7.5 | 1 | Not applicable | Y |
| | Tuber Flea Beetle | | Ground | 10 | 10 | | | |
| | Potato aphid<br>Buckthorn Aphid | | | | | | | |
| | European corn borer | EC | Ground | 12.5 | 12.5 | | | |
| Soybeans | Bean leaf beetle<br>Japanese beetle<br>Soybean aphid | SU | Ground and aerial | 6.5 | 19.5 | 3 | 5 | Y |
| Sugarbeets | Cutworm | EC | Ground and aerial | 10 | 10 | 1 | Not applicable | Y |
| Sunflower | Sunflower beetle (adults) | EC and SU | Ground | 5 | 5 | 1 | Not applicable | Y |
| | Sunflower beetle (adults and larvae) | | Aerial | 5 | 5 | 1 | | |
| Wheat | Cutworm | EC and SU | Ground and aerial | 10 | 10 | 1 | Not applicable | Y |
| | Grasshopper | EC and SU | Ground | 7.5 | 22.5 | 3 | 5 | Y |
| | | | Aerial | | 15 | 2 | | |
| Use-site Category #13 & 16: Terrestrial Food Crops and Industrial and Domestic Vegetation Control for non-Food Sites | | | | | | | | |
| Rangeland / Pastures / Roadsides | Grasshopper | EC<br>SU | Ground | 7.5 | 22.5 | 3 | 5 | Y, M |
| Use-site Category #14: Terrestrial Food Crops | | | | | | | | |
| Asparagus | Asparagus beetle | EC<br>SU | Ground | 10 | 30 | 3 | 7 | Y |
| Blueberries (highbush and lowbush) | Leaf tier | EC and SU | Ground | 7.5 | 22.5 | 3 | 5 | Y |
| | Brace spanworm | | | 6.25 | 18.75 | | | |
| | Blueberry aphid | SU | | 5.6 | 16.8 | | | |
| Broccoli | Cabbage looper<br>Imported cabbageworm<br>Diamondback moth | EC and SU | Ground | 10 | 80 | 8 | 10 | Y |
| | Aphids<br>Crucifer flea beetle | SU | | 6.5 | 19.5 | 3 | 5 | |

| Sites | Pests | Formulation Type[1] | Application Methods and Equipment | Application Rate (g a.i./ha) | | Maximum Number of Applications per Year | Typical Number of Days Between Applications | Supported Use?[2] |
|---|---|---|---|---|---|---|---|---|
| | | | | Maximum Single | Maximum Cumulative | | | |
| Broccoli (high organic or muck soils) | Cabbage looper<br>Imported cabbageworm<br>Diamondback moth | EC and SU | Ground | 10 | 10 | 1 | Not applicable | Y |
| Brussels sprouts | Cabbage looper<br>Imported cabbageworm<br>Diamondback moth | EC and SU | Ground | 10 | 80 | 8 | 10 | Y |
| | Aphids<br>Crucifer flea beetle | SU | | 6.5 | 19.5 | 3 | 5 | |
| Brussels sprouts (high organic or muck soils) | Cabbage looper<br>Imported cabbageworm<br>Diamondback moth | EC and SU | Ground | 10 | 10 | 1 | Not applicable | Y |
| Cabbage | Cabbage looper<br>Imported cabbageworm<br>Diamondback moth<br>Flea Beetle | EC and SU | Ground | 10 | 80 | 8 | 10 | Y |
| | Aphids<br>Crucifer flea beetle | SU | | 6.5 | 19.5 | 3 | 5 | |
| Cabbage (high organic or muck soils) | Cabbage looper<br>Imported cabbageworm<br>Diamondback moth | EC and SU | Ground | 10 | 10 | 1 | Not applicable | Y |
| Cauliflower | Cabbage looper<br>Imported cabbageworm<br>Diamondback moth | EC and SU | Ground | 10 | 80 | 8 | 10 | Y |
| | Aphids<br>Crucifer flea beetle | SU | | 6.5 | 19.5 | 3 | 5 | |
| Cauliflower (high organic or muck soils) | Cabbage looper<br>Imported cabbageworm<br>Diamondback moth | EC and SU | Ground | 10 | 10 | 1 | Not applicable | Y |
| Cavalo broccolo | Aphids<br>Cabbage looper<br>Crucifer flea beetle<br>Diamondback moth<br>Imported cabbageworm | SU | Ground | 6.5 | 19.5 | 3 | 5 | Y |
| Chinese broccoli | Aphids<br>Cabbage looper<br>Crucifer flea beetle<br>Diamondback moth<br>Imported cabbageworm | SU | Ground | 6.5 | 19.5 | 3 | 5 | Y |
| Chinese mustard cabbage | Aphids<br>Cabbage looper<br>Crucifer flea beetle<br>Diamondback moth<br>Imported cabbageworm | SU | Ground | 6.5 | 19.5 | 3 | 5 | Y |

| Sites | Pests | Formulation Type[1] | Application Methods and Equipment | Application Rate (g a.i./ha) | | Maximum Number of Applications per Year | Typical Number of Days Between Applications | Supported Use?[2] |
|---|---|---|---|---|---|---|---|---|
| | | | | Maximum Single | Maximum Cumulative | | | |
| Kale | Cabbage looper<br>Imported cabbageworm<br>Diamondback moth<br>Purplebacked cabbageworm | EC and SU | Ground | 10 | 80 | 8 | 10 | Y |
| Kohlrabi | Aphids<br>Cabbage looper<br>Crucifer flea beetle<br>Diamondback moth<br>Imported cabbageworm | SU | Ground | 6.5 | 19.5 | 3 | 5 | Y |
| Lentils | Cutworm | EC | Ground and aerial | 10 | 10 | 1 | Not applicable | Y |
| | Grasshopper | | Ground | 7.5 | 22.5 | 3 | 5 | |
| | | | Aerial | | 15 | 2 | | |
| | | SU | Ground | 6 | 18 | 3 | | |
| | | | Aerial | | 12 | 2 | | |
| Oilseed mustard | Beet webworm<br>Flea beetle<br>Lygus bug<br>Grasshopper | EC | Ground | 7.5 | 7.5 | 1 | Not applicable | Y, M |
| | Flea beetle<br>Clover cutworm<br>Bertha armyworm<br>Diamondback moth<br>Lygus bug<br>Grasshopper | | Aerial | | | | | |
| | Cabbage seedpod weevil | | Ground and aerial | 10 | 10 | 1 | | |
| Napa Chinese cabbage | Aphids<br>Cabbage looper<br>Crucifer flea beetle<br>Diamondback moth<br>Imported cabbageworm | SU | Ground | 6.5 | 19.5 | 3 | 5 | Y |
| Onions | onion thrips | EC | Ground | 10 | 10 | 1 | Not applicable | Y, M |
| Peaches | Oriental fruit moth | EC | Ground | 10 | 10 | 1 | Not applicable | Y |
| | Peach twig borer | SU | | | | | | |
| Pears | Pear psylla, nymphs | EC | Ground | 17.5 | 52.5 | 3 | 12 | Y |
| | Pear phyla, adults | SU | | | | | | |
| | Pear psylla, overwintering adults (B.C. only) | EC | | 10 | 30 | 3 | 12 | Y |
| | | SU | | | | | | |
| | Oriental fruit moth | EC | | 12.5 | 37.5 | 3 | 12 | Y, M |
| Peppers | European corn borer | EC | Ground | 15 | 45 | 3 | 5 | Y |
| | | SU | | | | | | |
| Tobacco | Cutworm | EC | Ground | 20 | 20 | 1 | Not applicable | Y |

| Sites | Pests | Formulation Type[1] | Application Methods and Equipment | Application Rate (g a.i./ha) | | Maximum Number of Applications per Year | Typical Number of Days Between Applications | Supported Use?[2] |
|---|---|---|---|---|---|---|---|---|
| | | | | Maximum Single | Maximum Cumulative | | | |
| (ground) | | SU | | | | | | |
| Tobacco (ground with rye or wheat cover crop) | Cutworm | EC<br>SU | Ground | 5 | 5 | 1 | Not applicable | Y |
| Saskatoon berries | Apple curculio<br>Hawthorn weevil<br>Leaf miner<br>Lygus bug (tarnished plant bug)<br>Saskatoon bud moth<br>Sawfly | EC | Ground | 10 | 30 | 3 | 5 | Y |
| Strawberries | Tarnished plant bug | EC<br>SU | Ground | 10 | 20 | 2 | 5 | Y |
| Tomatoes | Colorado potato beetle | EC<br>SU | Ground | 7.5 | 22.5 | 3 | 5 | Y |
| | Tomato hornworm | SU | | 6.5 | 19.5 | 3 | | |
| Tomatoes (high organic or muck soils) | Colorado potato beetle | EC<br>SU | Ground | 7.5 | 7.5 | 1 | Not applicable | Y |
| Use-site Category # 16: Industrial and Domestic Vegetation Control for Non-food Sites | | | | | | | | |
| Chokeberry shelterbelts | Prairie tent caterpillar<br>Ugly nest caterpillar<br>Fruittree leafroller | EC | Ground | 13.8 | 13.8 | 1 | Not applicable | Y, M |
| Roadsides | Grasshopper | EC | Ground | 7.5 | 22.5 | 3 | 5 | Y |
| Shelterbelts | Willow sawfly | EC | Ground | 27 | 27 | 1 | Not applicable | Y |
| | Blister beetle<br>Grey willow leaf beetle | | | 45 | 45 | | | |
| | Caragana aphid<br>Eastern spruce budworm<br>Spruce coneworm<br>Spring spruce needle moth<br>Spotted poplar aphid<br>Forest tent caterpillar<br>Prairie tent caterpillar | | | 135 | 135 | | | |
| | Forest tent caterpillar | | Aerial | 7.5 | 7.5 | | | |
| | Forest tent caterpillar | SU | Ground | 67.5 | 67.5 | | | |
| Use-site Category # 5: Greenhouse Food Crops | | | | | | | | |
| Tobacco greenhouse | Cutworm | EC<br>SU | Ground | 20 | 60 | 3 | 5 | Y |
| Use-site Category # 6: Greenhouse Non-Food Crops | | | | | | | | |

| Sites | Pests | Formulation Type[1] | Application Methods and Equipment | Application Rate (g a.i./ha) | | Maximum Number of Applications per Year | Typical Number of Days Between Applications | Supported Use?[2] |
|---|---|---|---|---|---|---|---|---|
| | | | | Maximum Single | Maximum Cumulative | | | |
| Ornamentals (greenhouse) | Western flower thrips | EC and SU | Ground | 25 | 75 | 3 | 5 | Y, M |
| Use-site Category # 7, 13 & 14: Industrial Oil Seed Crops and Fiber Crops, Terrestrial Food Crops and Terrestrial Food Crops | | | | | | | | |
| Canola<br>Rapeseed | Beet webworm<br>Flea beetle<br>Lygus bug<br>Grasshopper | EC | Ground | 7.5 | 7.5 | 1 | Not applicable | Y |
| | Flea beetle<br>Clover cutworm<br>Bertha armyworm<br>Diamondback moth<br>Lygus bug<br>Grasshopper | | Aerial | | | | | |
| | Cabbage seedpod weevil | | Ground | 10 | 10 | | | |
| | | | Aerial | | | | | |
| | Flea beetle | SU | Ground | 7.5 | 7.5 | | | |
| | | | Aerial | | | | | |
| Corn, seed | European corn borer | EC | Ground | 15 | 45 | 3 | 5 | Y |
| | Western bean cutworm | | | | | | | Y, M |
| | European corn borer | SU | | | | | | Y |
| Mustard | Beet webworm<br>Flea beetle<br>Lygus bug<br>Grasshopper | EC | Ground | 7.5 | 7.5 | 1 | Not applicable | Y |
| | Flea beetle<br>Clover cutworm<br>Bertha armyworm<br>Diamondback moth<br>Lygus bug<br>Grasshopper | | Aerial | | | | | |
| | Cabbage seedpod weevil | | Ground | 10 | 10 | | | |
| | | | Aerial | | | | | |
| | Flea beetle | SU | Ground | 7.5 | 7.5 | | | |
| | | | Aerial | | | | | |
| Use-site Category # 30: Turf | | | | | | | | |
| Turf (including residential lawns, golf courses, athletic fields, recreational areas, sod farms, and other turf areas in commercial sites) | Chinch bug<br>Sod webworm<br>Cutworm<br>Ants<br>Ticks | SU | Ground | 60 | 120 | 2 | 14 | Y, M |

[1] EC = Emulsifiable Concentrate or Emulsion, SU = Suspension

[2] Y = use is supported by the registrant; N = use is not supported by the registrant; P = the registrant partially supports the use pattern; and M = use was registered as a User Requested Minor Use Label Expansion (URMULE).

# Appendix III Toxicology Assessment for Deltamethrin

| Study/Species | Results/Effects |
|---|---|
| **Metabolism/Toxicokinetic Studies** | |
| Metabolism<br>Mice<br>PMRA# 2007547 | Major metabolic pathways in mice are similar (but not identical) to those in rats.<br>6 Monohydroxy ester metabolites and 1 dihydroxy metabolite were identified in feces. Major metabolites in mice were Br2-carboxylic acid, trans-OH-Br2-carboxylic acid and their glucuronide and sulphate conjugates. 3-Phenoxy benzaldehyde, 3-phenoxyl benzyl alcohol and its glucuronide, and the glucuronide of 3-(4-hydroxy phenoxy)benzyl alcohol and 3-hydroxy-3-phenoxy benzoic acid were also detected in mice. |
| Absorption, Distribution, Metabolism, Elimination<br>Rats<br>PMRA# 2007547<br>PMRA# 1743296<br>PMRA# 2007548<br>PMRA# 2007549<br>PMRA# 2007551<br>PMRA# 2007550 | Absorption<br>Absorption from the gastrointestinal tract was rapid with peak blood levels occurring within 1 to 2 hours of exposure. Absorption was incomplete, with only 18% bioavailability of a 2 mg/kg bw dose.<br>Distribution<br>Distribution to blood was rapid; over 80% of the deltamethrin in blood was present in plasma. Distribution to well perfused tissues (i.e., brain, liver, kidney) was rapid at all doses tested. Concentrations in brain tissue were substantially lower than blood at all time points and were less than 0.5% of the systemically absorbed dose. Poorly perfused tissues (i.e., skin, fat, muscle) accumulated larger amounts and served as slow-release depots. Tissue concentrations were dose-dependent. Tissue residues were generally below 0.1 ppm, 7 days following acute or repeated exposure. Levels in fat 7 days following acute (0.04-0.8 µg/g) or repeated (0.05-0.7 µg/g) exposure were low. Acute oral exposure in pre-weanling, weanling and adult rats resulted in tissue concentrations and neurological effects which were inversely related to age. Brain tissue concentrations in pre-weanling and weanling rats were 5- to 8-fold higher than brain tissue concentrations in adults receiving the same dose.<br>Elimination<br>The majority of deltamethrin was eliminated within 24 hours after exposure with an elimination half-life of 17.8 hours. Deltamethrin radiolabelled in the cyano position was more slowly eliminated than deltamethrin radiolabelled in the benzyl or dimethyl positions. Equivalent amounts were eliminated in the urine and feces regardless of dosing regimen. Brain, kidney and blood had the fastest tissue elimination while fat, skin and muscle had the slowest elimination. Elimination half-lives in adult brain tissue ranged from 12.5 to 19.5 hours.<br>Metabolism<br>There are two major metabolic pathways for deltamethrin. The first involves oxidation by cytochrome P450 oxidase in liver microsomes to (2', 4' or 5')-hydroxyphenoxy)-benzoic acid and conjugation with sulphate and glucuronide. The second pathway involves hydrolysis by carboxylesterases in plasma and liver microsomes to 3-phenoxybenzoic acid followed by conjugation with sulphate and glucuronide. Metabolites identified in urine and feces include 2', 4' or 5'-hydroxy-deltamethrin, 3-(2,2-dibromovinyl)-2,2-dimethyl-cyclopropane-carboxylic acid and its conjugates and hydroxylate derivatives, 3-phenoxybenzoic acid and its conjugates, 3-(2' or 4'-hydroxyphenoxy)benzoic acid and its conjugates, thiocyanate and 2-iminothiazolidine-4-carboxylic acid. The parent compound was also identified in feces. |

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| Absorption, Distribution, Metabolism, Elimination<br>Humans | No clinical signs of toxicity. Peak plasma levels were detected 1 to 2 hours post-exposure. The elimination half-life in plasma was 10 to 11.5 hours. The elimination half-life in urine was 10 to 11.5 hours. Urinary elimination accounted for 51% to 59% of the administered dose; 90% was eliminated within 24 hours. At termination, fecal elimination accounted for 10% to 26% of the administered dose. After 96 hours, total elimination in urine and feces was 64% to 77% of the administered dose. |
| **Acute Toxicity Studies** | |
| Acute Oral Toxicity<br>Rats<br>**PMRA # [illegible]**<br>**PMRA # [illegible]**<br>**PMRA # [illegible]**<br>**PMRA # [illegible]**<br>**PMRA # [illegible]** | $LD_{50}$ (in sesame oil) = 128/139 mg/kg bw (♂/♀)<br>$LD_{50}$ (in peanut oil) = 52/31 mg/kg bw (♂/♀)<br>$LD_{50}$ (in PEG) = 67/86 (♂/♀)<br>$LD_{50}$ (in 1% carboxymethyl cellulose) = > 5000 mg/kg bw; no mortality<br>Clinical signs following exposure to deltamethrin in oil or PEG included stained fur, excessive grooming, excessive salivation, decreased activity, [illegible], weakness, difficulty walking, general motor incoordination, choreoathetosis, clonic seizures and death. |
| Acute Oral Toxicity<br>Beagle Dogs<br>**PMRA # [illegible]**<br>**PMRA # [illegible]** | **Considered supplemental.**<br>$LD_{50}$ > 300 mg/kg bw (♂/♀)<br>**≥ 100 mg/kg bw:** vomiting, diarrhea, stiffness of hind legs with recovery at 72 hours; no mortality and no effect on bw |
| Acute Dermal Toxicity<br>Wistar Rats<br>**PMRA # [illegible]** | $LD_{50}$ > 2000 mg/kg bw (♂/♀)<br>No mortality or clinical signs, and no effects on body weight or gross pathology in either sex.<br>**Low Dermal Toxicity** |
| Acute Inhalation Toxicity – Whole Body Exposure<br>Sprague Dawley Rats<br>**PMRA # [illegible]** | $LC_{50}$ = 0.6 mg/L<br>Moderate irritation at ≥ 0.05 mg/L<br>**Moderate Inhalation Toxicity** |
| Acute Inhalation Toxicity – Whole Body Exposure<br>Sprague Dawley Rats<br>**PMRA # [illegible]** | $LC_{50}$ = 2.2 mg/L (♂/♀)<br>≥ 1 mg/L: impaired hindlimb function, ↓ bw<br>≥ 1.8 mg/L: pulmonary congestion<br>**Low Acute Toxicity** |
| Acute Dermal Irritation<br>New Zealand Rabbits<br>**PMRA # [illegible]** | No erythema or edema up to 72 hours after application.<br>**Not a Dermal Irritant** |

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| Acute Dermal Irritation<br>♀ New Zealand White Rabbits<br>**PMRA # 1549340** | No systemic effects and no dermal irritation.<br>**Not a Dermal Irritant** |
| Acute Dermal Irritation<br>New Zealand Rabbits | No signs of dermal irritation.<br>**Not a Dermal Irritant** |
| Dermal Sensitization Buehler Patch Test<br>Hartley Guinea-Pigs<br>**PMRA # 1549343** | No treatment-related effects.<br>Positive controls verified protocol.<br>**Not a Dermal Sensitizer** |
| Dermal Sensitization - Modified Maximization Test<br>Hartley Guinea-Pigs<br>**PMRA# 1204894**<br>**PMRA #1549342** | No treatment-related effects.<br>**Not a Dermal Sensitizer** |
| Eye Irritation<br>**PMRA #1549338** | No systemic effects and no eye irritation.<br>**Non-Irritating (♀)** |
| Eye Irritation<br>New Zealand White Rabbits<br>**PMRA# 1204891** | Transient irritation was observed up to 24 hours. No irritation was observed after 72 hours.<br>**Non Irritating (♂)** |
| Eye Irritation<br>New Zealand White Rabbits | Marked conjunctival redness, slight to marked discharge and slight swelling after 1 hour. No irritation was observed after 72 hours.<br>**Non Irritating (both sexes)** |

| Study/Species | NOAEL (mg/kg bw/day) | Results/Effects |
|---|---|---|
| **Subchronic Toxicity Studies** | | |
| 4-Week Dietary Toxicity<br>OFA Swiss Mice | | **Considered supplemental.**<br>No treatment-related histopathology.<br>**≥ 30 mg/kg bw/day:** ↓ food consumption, ↓ relative liver weight, ↓ absolute kidney weight<br>**60 mg/kg bw/day:** mortality, ↓ bw |

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| 12-Week Dietary Toxicity<br>CD1 Mice | | **Considered supplemental.**<br>No treatment-related changes in haematology, organ weights, gross pathology or histopathology.<br>**≥ 600/740 mg/kg bw/day:** dyspnoea, piloerection, walking with arched backs, mortality; clonic convulsions (♂); ↓ bw (♀)<br>**1300 mg/kg bw/day:** clonic convulsions |
| 13-Week Oral Toxicity - Gavage<br>Sprague Dawley Rats<br>**PMRA# 1284898**<br>**PMRA # 1549344** | 1 | **≥ 2.5 mg/kg bw/day:** ss ↓ bw<br>**10 mg/kg bw/day:** slight transient hypersensitivity at week 6 (♂); additional details were not presented |
| 13-Week Dietary Toxicity<br>CD(SD)BR Rat<br>**PMRA #1549345** | LOAEL = 2.7 (♀)<br>NOAEL = 24 (♂) | **≥ 2.7 mg/kg bw/day:** ↓ bw, ↓ bwg (♀)<br>**≥ 24/31 mg/kg bw/day:** ↓ bw, ↓ bwg (♀)<br>**≥ 72/84 mg/kg bw/day:** 3 deaths, transient emaciated appearance, uncoordinated movements, unsteady gait, hunched posture, ↑ sensitivity to sound, piloerection, gasping, tremors, poor grooming, ↓ food and water consumption; ↓ mean bwg (♂)<br>**≥ 241/272 mg/kg bw/day:** mortality, severe neurological signs, emaciation, closed eyes, convulsions, enlarged cervical lymph nodes, minimal adipose tissue, distention of the GI tract, pale spleen, small seminal vesicles and prostrate, thin uterus. Animals terminated by day 16.<br>**425/444 mg/kg bw/day:** mortality; animals terminated by day 9. |
| 13-Week Oral Toxicity-Gelatin Capsule<br>Beagle Dogs<br>**PMRA#1549349** | 1 | **Treatment:**<br>**≥ 0.1 mg/kg bw/day:** non dose-related ↓ flexor reflex at 5 weeks only; questionable biological significance<br>**≥ 1 mg/kg bw/day**: non dose-related ↓ patellar reflex at 12 weeks; questionable biological significance<br>**≥ 2.5 mg/kg bw/day:** abnormal EEG, ↑ incidence of |

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| | | liquid feces, ↓ gag reflex at 5 or 12 weeks, dilation of pupils, ↓ bwg<br>**10 mg/kg bw/day:** ↓ tactile placing reflex at 5 weeks, ↑ vomiting (mainly 1st week of dosing), jerking movements, ↓ patellar reflex at 5 weeks, transient tremors, unsteadiness, salivation, ↓ food consumption and ↓ bw (first 2 weeks of dosing)<br>No effects on blink reflex<br>**Recovery:**<br>**0.1 mg/kg bw/day:** recovery not assessed<br>**≥ 1 mg/kg bw/day:** effects on EEG, gag reflex, flexor reflex, tactile placing reflex and tremors were recovered. Incidents of liquid feces which decreased as recovery progressed. |
| 13-Week Oral Toxicity – Gelatin Capsule<br>Beagle Dogs<br>**PMRA#1549352** | 10 | **Treatment:**<br>**50 mg/kg bw/day:** body tremors, unsteady gait, vomiting, salivation, chewing of extremities, shaking head, hunched posture, ↓ bwg, ↓ food consumption<br>**Recovery:**<br>No treatment-related effects following recovery. |
| 1-Year Oral Toxicity Study – Gelatin Capsule<br>Beagle Dogs<br>**PMRA# 1549346** | 1 | **≥ 10 mg/kg bw/day:** ↑ incidence of liquid feces, vomiting, chewing/scratching of extremities, ↓ bwg, tremors, abnormal gait, locomotor impairment, unsteadiness, un-coordinated hindlimb gait, splayed limbs, ↓ serum albumin and calcium; dose-related ↓ packed cell volume, ↓ Hb (♂)<br>**50 mg/kg bw/day:** abnormal head movements, inability to stand, ↓ food consumption (♂) |
| 14-Day Inhalation Toxicity - Whole Body Exposure<br>CD Rats<br>**PMRA# 1549348** | LOAEL= 0.78<br>NOAEL not determined | **≥ 0.003 mg/L (0.78 mg/kg bw/day):** ↓ food consumption, drooling, licking, blinking, scratching, agitated grooming; slight ↓ bwg (♂)<br>**≥ 0.009 mg/L (2.5 mg/kg bw/day)**: peripheral vasodilation<br>**0.056 mg/L (14.7 mg/kg bw/day)** ataxia, walking with arched backs |
| 3-Week Dermal Toxicity<br>Sprague Dawley Rats<br>**PMRA #1549347** | 1000 | No adverse treatment-related effects. |
| **Neurotoxicity Studies** | | |
| Acute Neurotoxicity Study – Gavage | | **Considered supplemental.** |

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| (Non-Guideline Motor Activity)<br>Long-Evans Rats<br>**PMRA# 2007552**<br>**PMRA# 2007553** | | ≥ 3.0 mg/kg bw (in corn oil or glycerol formal): ↓ motor activity<br>≥ 300 mg/kg bw (carboxymethyl cellulose): ↓ motor activity<br>Deltamethrin induced dose-dependent reductions in motor activity regardless of vehicle, though the time-course of effectiveness varied with the vehicle used. Peak effects were noted 1 to 2 hours post-exposure. Motor activity in all groups recovered 8 hours following exposure. |
| Acute Oral Neurotoxicity Study – Gavage<br>(Non-Guideline Motor Activity)<br>Long-Evans Rats<br>**PMRA #2007554** | 1.27 ($BMDL_{10}$) | ↓ motor activity<br>$BMD_{10}$ = 1.54 mg/kg bw<br>$BMDL_{10}$= 1.27 mg/kg bw (best fit)<br>$BMD_{20}$= 3.08 mg/kg bw<br>$BMDL_{20}$= 2.53 mg/kg bw |
| Acute Oral Neurotoxicity Study – Gavage<br>(Non-Guideline Motor Activity and Acoustic Startle Response)<br>Long-Evans Rats<br>**PMRA #2007555** | | **Considered supplemental.**<br>**Motor activity:**<br>**≥ 2 mg/kg bw:** ss dose-related ↓ motor activity at 1- and 2-hours post-exposure<br>**Acoustic Startle Response**:<br>**≥ 2 mg/kg bw**: dose-related ↓ amplitude and ↑ latency of acoustic startle response |
| Acute Oral Neurotoxicity Study –Gavage<br>Sprague Dawley Rats<br>**PMRA# 1549374** | 5 | **≥ 15 mg/kg bw:** On the day of treatment, slight salivation and impaired mobility (♂); slightly soiled fur (♀)<br>**50 mg/kg bw:** On the day of treatment, mortality (1 animal/sex), altered posture, tremors, biting, drooping eyelids, severe salivation, soiled fur, ↑ mean time to first step, impaired mobility and gait, hindlimbs splayed/dragging, clonic and tonic convulsions, low arousal, writhing, ↓ mean number of rears, absent approach response, ↓ touch response, ↓ startle response, ↓ tail pinch response, no reaction in olfactory orientation, ↓ mean forelimb and hindlimb grip strength, ↓ rotarod performance, muscular rigidity; ↓ mean hindlimb footsplay (♂)<br>Complete recovery was noted after 7 and 14 days. |

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| | | No effects on eye blink response, brain weight or brain morphometrics. No treatment-related neuropathological lesions. |
| Acute Oral Neurotoxicity Study – Gavage<br>CD (SD)IGS BR Rats<br>**PMRA#2007556**<br>**PMRA# 2043579** | LOAEL= 12.5<br>NOAEL not determined | **≥ 12.5 mg/kg bw:** ↓ bw, altered posture, salivation, abnormal gait, stereotypic behavior, ↑ resistance to removal and handling, ↓ rearing, ↓ forelimb and hindlimb grip strength, ↓ rotarod performance, ↓ hindlimb footsplay<br>**≥ 25 mg/kg bw:** clonic convulsions, stained fur, low arousal, hindlimb weakness, red deposits around nose, ↓ air righting reflex, ↓ mean body temperature<br>**35 mg/kg bw:** biting, drooping eyelids, ↑ mean time to first step, ↑ touch response, ↑ startle response, absence of hindlimb extension<br>No effect on blink response. |
| Acute Comparative Oral Neurotoxicity – Gavage<br>11-, 21- or 72-day old Long Evans Rats<br>**PMRA#1857302**<br>**PMRA#1857303** | **21-Day Old Weanling Rats:**<br>LOAEL= 1<br>NOAEL not determined<br>**Adult Rats:**<br>LOAEL= 2<br>NOAEL not determined | **Acute Oral Toxicity:**<br>$LD_{50}$'s for 11-, 21- and 72-day old ♂ rats were 5.1, 11 and 81 mg/kg bw, respectively.<br>Profuse salivation, tremors and choreoathetosis were observed in all groups.<br>**Acoustic Startle Response (ASR):**<br>21-Day Old Weanlings:<br>**≥ 1 mg/kg bw:** ss dose-related ↓ ASR amplitude<br>**≥ 2 mg/kg bw:** mild salivation<br>**4 mg/kg bw:** burrowing behaviour, spontaneous vocalizations<br>Adults:<br>**≥ 2 mg/kg bw:** ss dose-related ↓ ASR amplitude<br>**6 mg/kg bw:** burrowing and mild salivation (♂)<br>Adults were not tested at 1 mg/kg bw.<br>**Brain Tissue Analysis:**<br>Following exposure in weanling and adults to a behaviorally-active dose (4 mg/kg bw), the concentration of deltamethrin in the brain was 2-fold higher in weanlings, compared to adults. |
| 13-Week Dietary Neurotoxicity Study<br>Sprague Dawley Rats | 14/16 (♂/♀) | **54/58 mg/kg bw/day (♂/♀):** mortality, ↓ food consumption, ↓ bw, unsteady and impaired gait, impaired mobility, hypersensitivity to noise, splayed hindlimbs, impaired righting reflex, ataxia, side to side rocking, ↓ hindlimb extensor strength, ↓ |

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| **PMRA#1549375** | | hindlimb and forelimb grip strength, piloerection, convulsions, stained fur, altered posture<br>No effect on blink reflex. |
| 7-Day Oral Developmental Neurotoxicity Study – Gavage<br>(Non-Guideline)<br>NMRI Mice<br>**PMRA# 2007557**<br>**PMRA#2007558** | | **Considered supplemental.**<br>**PND 17 Mice:**<br>**≥ 0.7 mg/kg bw/day:** ↑ binding sites in muscarinic and nicotinic receptors in the cerebral cortex<br>**1.2 mg/kg bw/day:** choreoathetosis within 1 hour, ↓ binding sites in muscarinic receptors in hippocampus<br>**Adult (4 Month Old) Mice:**<br>**≥ 0.7 mg/kg bw/day:** ↑ locomotion, ↑ total activity, ↑ high-affinity binding sites and ↓ low-affinity binding sites in muscarinic receptors in cerebral cortex, ↑ density of nicotinic receptors in cerebral cortex |
| Oral Developmental Neurotoxicity Study – Diet<br>Wistar Rat<br>Pilot Study<br>**PMRA # 1549376** | | **Considered supplemental.**<br>**Maternal Toxicity:**<br>**12.5 mg/kg bw/day:** cannibalization of offspring during the first week of lactation; quantitative data were not presented<br>**Offspring Toxicity:**<br>**12.5 mg/kg bw/day:** ↑ incidence of pup loss (including cannibalization by dam) during the first week of lactation; quantitative data were not presented.<br>Mean concentrations of deltamethrin in the brain of pups on PND 10, 14 or 16 (34.6, 37.2 or 32.1 ppb, respectively) demonstrate that the brain is exposed to deltamethrin during lactation. No additional quantitative data were presented in the report.<br>Pup loss was not observed in the main study. |
| Oral Developmental Neurotoxicity Study– Diet<br>Wistar Rats<br>**PMRA#1549520**<br>**PMRA#1549377**<br>**PMRA#1857307**<br>**PMRA#1857304** | Maternal = 6.8<br>Offspring = 6.8 | **Maternal Toxicity:**<br>No deaths, clinical signs of toxicity or treatment-related effects on reproductive indices. Brain weights were not assessed.<br>**16.1 mg/kg bw/day:** ↓ bw, ↓ bwg and ↓ food consumption throughout gestation and lactation<br>**Offspring Toxicity:** |

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|---|---|---|
| **PMRA#1857308** | | No treatment-related effects on motor activity, auditory startle, learning and memory, brain morphometrics or neuropathology.<br>**16.1 mg/kg bw/day:** ↓ bw on PND 4, ↓ bwg PND 1-4 and PND 4-11; ↑ vocalizations and resistance to handling, delayed onset of balanopreputial separation due to ↓ bw (♂); ↓ fixed brain weight on PND 75 only (♀) |
| Oral Developmental Neurotoxicity - Gavage<br>(Non-Guideline)<br>Sprague Dawley Rats<br>**PMRA# 1549407** | | **Considered supplemental.**<br>**Maternal Toxicity**<br>**5 mg/kg bw/day:** ↓ survival on PND 22<br>**Offspring Toxicity**<br>**2.5 mg/kg bw/day:** ↓ bw on PND 22 (♂)<br>**5 mg/kg bw/day:** ↓ bw on PND 22 (♂/♀); bw effects recovered by PND 36 |
| **Chronic Toxicity/Oncogenicity Studies** | | |
| 2-Year Dietary Carcinogenicity<br>CD-1 Mice<br>**PMRA #1549362** | 16/20 (♂/♀) | **≥ 155/190 mg/kg bw/day**: ↑ incidence of dermal ulceration and cellulitis (related to paresthesia); slight ↑ mortality after week 78 (♀)<br>**315/395 mg/kg bw/day:** emaciation; cutaneous lesions, ↓ bw and bwg (♂); dyspnoea, ulceration, subacute cellulitus (♀)<br>**No evidence of carcinogenicity** |
| 2-Year Dietary Chronic Toxicity/ Carcinogenicity<br>Sprague-Dawley Rat<br>**PMRA#1204908**<br>**PMRA# 1549353** | 1/3.2 (♂/♀) | **2.5 mg/kg bw/day:** ↑ incidence of conjunctivitis, ↓ bw |
| 2-Year Dietary Chronic Toxicity/ Carcinogenicity<br>CD(SD)BR Rats<br>**PMRA #1549356** | 1.1/1.5 (♂/♀) | **≥ 5.4/7.3 mg/kg bw/day:** ↑ cystic degeneration ("ballooned cells") in liver (♂); transient ↓ lymphocytes and leukocytes (♀)<br>**≥ 22/30 mg/kg bw/day:** uncoordinated movement of limbs, splayed limbs, unsteady gait, ↓ bwg ; ↑ incidence of eosinophilic hepatocytes (♂)<br>**36/47 mg/kg bw/day:** transient ↓ lymphocytes and leukocytes (♂); ↓ plasma cholesterol, ↑ plasma glucose and ↓ plasma protein throughout treatment, |

| | | |
|---|---|---|
| | | ↓ bwg (week 1), ↓ food consumption (♀)<br>**No evidence of carcinogenicity** |
| 2-Year Dietary Chronic Toxicity<br>Beagle Dog<br>**PMRA#1204918**<br>**PMRA #1204919** | 0.025 | **≥ 0.25 mg/kg bw/day:** absent blink reflex in ♀ (right eye only) at 1 year and 2 years; considered treatment-related<br>**1 mg/kg bw/day:** absent blink reflex in ♂ (both eyes) at 2 years; absent blink reflex in ♀ (both eyes) at 2 years |
| **Developmental/Reproductive Toxicity Studies** | | |
| Dietary 2-Generation Reproductive Toxicity<br>Sprague-Dawley Rats<br>**PMRA #1549367** | Parental = 5.5/6.2<br>Reproductive = 21.5/23.5<br>Offspring = NOAEL not established due to absence of brain histopathology data for low- and mid-dose animals | **Parental Toxicity**<br>**21.5/23.5 mg/kg bw/day** (♂/♀): ↓ mean bw, ↓ mean bwg, ↓ food consumption, alopecia, skin lesions, ataxia, hypersensitivity, hyperactivity, salivation, stained fur, impaired righting reflex, splayed limbs, vocalization in $F_0$ and $F_1$; ↑ relative seminal vesicle weight and ↑ relative testes weight in $F_0/F_1$ ♂ at termination, ↑ relative epididymis weight in $F_0$ ♂ at termination; ↓ absolute testes weight and ↓ absolute epididymis weight in $F_1$ ♂; treatment-related mortality in 1 $F_0$ ♀<br>**Reproductive Toxicity**<br>No adverse effects.<br>**Offspring Toxicity**<br>**21.5/23.5 mg/kg bw/day** (♂/♀): ↓ mean pup bw throughout lactation in $F_1$ and $F_2$ pups, ↑ mortality in $F_1$ pups (PND 8 and PND 14), ↑ mortality in $F_1$ ♀ and ♂ within 8 days after weaning, ↓ lactation index, ataxia, impaired righting reflex, hyperactivity, splayed limbs, vocalization, salivation in $F_1$ pups (observations generally appeared early in the post-weaning phase), cerebral congestion and/or blood clots in brain in $F_1$ ♀ and ♂; considered treatment-related and adverse |
| Oral Developmental Toxicity - Gavage<br>CD-1 Mice<br>**PMRA# 1549407** | Maternal = 3<br>Developmental = 12 | **Maternal Toxicity:**<br>**≥ 6 mg/kg bw/day:** ↓ bwg, convulsions<br>**Developmental Toxicity**<br>No adverse effects. |
| Oral Developmental Toxicity - Gavage | Maternal = 10 | **Maternal Toxicity:**<br>No adverse effects. |

| | | |
|---|---|---|
| Swiss CD1 SPF Mice<br>**PMRA # 1204905**<br>**PMRA# 1549380** | Developmental = 0.1 | **Developmental Toxicity**<br>**1.0 mg/kg bw/day:** ↓ fetal bw, delayed ossification of sternebrae and paws |
| Oral Developmental Toxicity - Gavage<br>Sprague Dawley Rats<br>**PMRA#1204905**<br>**PMRA# 1549380** | Maternal = 1<br>Developmental = 1 | **Maternal Toxicity:**<br>**10 mg/kg bw/day:** ↓ bw<br>**Developmental Toxicity**<br>**10 mg/kg bw/day:** delayed ossification of sternebrae |
| Oral Developmental Toxicity - Gavage<br>CD VAF/Plus Rats<br>**PMRA# 1549379** | Maternal = 3.3<br>Developmental = 11 | **Maternal Toxicity**<br>**≥ 7 mg/kg bw/day:** ↑ mortality (1 dam after 10 days), salivation, piloerection, hypersensitivity, convulsions, ↓ bwg<br>**11 mg/kg bw/day:** ↑ mortality (14 dams after 1-2 days), anogenital staining, abnormal vocalization, hypersensitivity to external stimuli<br>**Developmental Toxicity**<br>No adverse effects. |
| Oral Developmental Toxicity - Gavage<br>Sprague-Dawley Rats<br>**PMRA# 1549407** | Maternal = 2.5<br>Developmental = 5 | **Maternal Toxicity**<br>**5 mg/kg bw/day:** ↓ bwg, mild salivation<br>**Developmental Toxicity**<br>No adverse effects. |
| Oral Developmental Toxicity - Gavage<br>New Zealand White Rabbits<br>**PMRA# 1549381** | Maternal = 25<br>Developmental = 25 | **Maternal Toxicity**<br>**100 mg/kg bw/day:** mortality and lung congestion in 1 dam on GD 27; considered treatment-related<br>**Developmental Toxicity**<br>**100 mg/kg bw/day:** wrist flexure, delayed ossification in hyoid body, pubic bones and tail vertebrae |
| Oral Developmental Toxicity - Gavage<br>New Zealand White Rabbits<br>**PMRA# 1549382**<br>**PMRA#1851512**<br>**PMRA# 1549383** | Maternal = 10<br>Developmental = 32 | **Maternal Toxicity**:<br>**32 mg/kg bw/day**: ↓ food consumption and ↓ bwg from GD 9 to 21<br>**Developmental Toxicity**:<br>No treatment-related effects |

| | | |
|---|---|---|
| Oral Developmental Toxicity - Gavage<br>New Zealand White Rabbits<br>**PMRA# 1549380** | Maternal = 16<br>Developmental = 4 | **Maternal Toxicity:**<br>No treatment-related effects.<br>**Developmental Toxicity:**<br>**16 mg/kg bw/day:** ↓ fetal bw |
| **In Vitro Genotoxicity Studies** | | |
| Gene mutation: Salmonella typhimurium TA 98, TA 1537, TA 1538, TA 100<br>**PMRA# 1204903**<br>**PMRA#1549384** | Negative | |
| Chromosomal Aberrations<br>Chinese Hamster Ovary Cells<br>**PMRA#1549390** | Negative | |
| Unscheduled DNA Synthesis<br>Rat Hepatocytes<br>**PMRA#1549392** | Negative | |
| **In Vivo Genotoxicity Studies** | | |
| Micronucleus Assay<br>Swiss CD-1 Mouse Bone Marrow Cells | **Considered supplemental.**<br>Negative | |
| Chromosomal Aberration Assay<br>♀ Swiss Mice<br>Bone Marrow Cells<br>**PMRA#2007547** | Negative following single or repeated exposure. | |
| Dominant Lethal Mutation – Oral<br>Swiss CD-1 Mice<br>**PMRA# 1549393** | **15 mg/kg bw:** ↑ mortality (♂)<br>Negative following single or repeated exposure. | |

| **Special Studies (Supplemental)** | |
|---|---|
| Oral Developmental Toxicity - Gavage<br>(Non-Guideline)<br>Wistar Rat<br>Special study of male reproductive effects<br>**PMRA# 2044455** | **Maternal Toxicity:**<br>No treatment-related clinical signs. No effects on bw, mating performance or pregnancy indices.<br>**Developmental Toxicity**<br>**4 mg/kg bw/day:** ↓ absolute and relative testicular, epididymal, prostrate and seminal vesicle weights, ↓ diameter of seminiferous tubules, ↓ sperm number, ↓ daily sperm production, ↓ testosterone levels in male offspring |
| In-Vitro Metabolism<br>Plasma and Hepatic Microsomes<br>10-, 21-, 40- or 90-day old ♂ Sprague-Dawley Rats<br>**PMRA# 2043578** | Clearance in plasma and liver increased with age due to progressive increases in $V_{max}$ for P450 and carboxylesterases. PND 10 and PND 21 $V_{max}$ values were not significantly different, nor were PND 40 or PND 90 $V_{max}$ values.<br>Hepatic P450s had a predominant role in deltamethrin biotraformation in young and adult rats. Clearance of deltamethrin by liver P450 was 7.1-fold higher in PND 90 rats, compared to PND 10 rats. |

## Table 2. Toxicology Endpoints for Use in Health Risk Assessment for Delamethrin

| | **RfD** | **Study NOAEL (or LOAEL)** | **CF[1] or target MOE** |
|---|---|---|---|
| **Acute Dietary** | ARfD= 0.003 mg/kg bw | LOAEL = 1 mg/kg bw<br>Acute oral comparative neurotoxicity study (decreased acoustic startle response amplitude in weanling rats) | 300 |
| **Chronic Dietary** | ADI= 0.003 mg/kg bw/day | LOAEL = 1 mg/kg bw/day<br>Acute oral comparative neurotoxicity study (decreased acoustic startle response amplitude in weanling rats) | 300 |
| **Short-, Intermediate- and Long-Term Dermal** | | NOAEL= 1000 mg/kg bw/day<br>Short-term dermal toxicity study in rats (limit dose) | 1000 |
| **Short-, Intermediate-and Long-Term Inhalation[2]** | | LOAEL = 1 mg/kg bw/day<br>Acute oral comparative neurotoxicity study (decreased acoustic startle response amplitude in weanling rats) | 300 |
| **Non Dietary Incidental Oral Ingestion** | | LOAEL = 1 mg/kg bw/day<br>Acute oral comparative neurotoxicity | 300 |

| | | | |
|---|---|---|---|
| | | study (decreased acoustic startle response amplitude in weanling rats) | |
| **Aggregate Risk – Oral and Inhalation**[2] | | LOAEL = 1 mg/kg bw/day<br>Acute oral comparative neurotoxicity study (decreased acoustic startle response amplitude in weanling rats) | 300 |
| **Aggregate Risk – Dermal** | | Not required | |
| **Carcinogenicity** | No evidence of carcinogenicity | | |

[1] CAF (Composite assessment factor) refers to the total uncertainty and *Pest Control Products Act* factors for dietary and residential risk assessment; MOE refers to the target margin of exposure for occupational assessment.

[2] Since an oral LOAEL was selected, an inhalation absorption factor of 100% (default value) is used in route-to-route extrapolation.

# Appendix IV Agricultural Mixer/Loader/Applicator and Postapplication Risk Assessment

## Table 1 Short-, Intermediate-, and Long-term Commercial Mixer, Loader, and Applicator Exposure and Risk Assessment

| Crop | Scenario | Application Equipment | ATPD | Max Rate (kg/ha or kg/L) | Dermal Exposure[a] (mg/kg/day) | Inhalation Exposure[b] (mg/kg/day) | MOE | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | Dermal[c] | Inhalation[d] |
| Barley, Canola, Flax, Lentil, Mustard (& Oilseed), Oats, Sugarbeet, Wheat | MLA | AirBlast | 20 ha/day | 0.033 kg/ha | 2.20 × 10^[illegible] | 1.89 × 10^[illegible] | 4500000 | 530000 |
| | | GB Custom | 360 ha/day | | 5.70 × 10^[illegible] | 1.17 × 10^[illegible] | 2600000 | 8700 |
| | | MP10G | 3800 L/day | 0.00033 kg/L | 2.69 × 10^[illegible] | 7.07 × 10^[illegible] | 580000 | 1400 |
| | | MP10W | 150 L/day | | 1.77 × 10^[illegible] | 6.46 × 10^[illegible] | 17000000 | 1200000 |
| | | Backpack | | | 1.02 × 10^[illegible] | 1.16 × 10^[illegible] | 9800000 | 860000 |
| | ML | Aerial - ML | 400 ha/day | 0.033 kg/ha | 2.76 × 10^[illegible] | 8.00 × 10^[illegible] | 5900000 | 110000 |
| | A | Aerial - A | | | 6.85 × 10^[illegible] | 5.50 × 10^[illegible] | 21000000 | 2900000 |
| Corn (Sweet) | MLA | AirBlast | 20 ha/day | 0.017 kg/ha | 5.30 × 10^[illegible] | 2.78 × 10^[illegible] | 3000000 | 560000 |
| | | GB Custom | 360 ha/day | | 5.08 × 10^[illegible] | 1.75 × 10^[illegible] | 1900000 | 5800 |
| | | MP10G | 3800 L/day | 0.000065 kg/L | 1.06 × 10^[illegible] | 6.68 × 10^[illegible] | 600000 | 2200 |
| | | MP10W | 150 L/day | | 1.11 × 10^[illegible] | 5.30 × 10^[illegible] | 90000000 | 1900000 |
| | | Backpack | | | 6.38 × 10^[illegible] | 7.28 × 10^[illegible] | 16000000 | 1400000 |
| | ML | Aerial - ML | 400 ha/day | 0.017 kg/ha | 5.80 × 10^[illegible] | 1.20 × 10^[illegible] | 2400000 | 8500 |
| | A | Aerial - A | | | 7.29 × 10^[illegible] | 5.25 × 10^[illegible] | 14000000 | 1900000 |
| Pastures, Rangeland | MLA | AirBlast | 20 ha/day | 0.0075 kg/ha | 1.03 × 10^[illegible] | 1.39 × 10^[illegible] | 6100000 | 72000 |
| | | GB Custom | 360 ha/day | | 2.60 × 10^[illegible] | 9.64 × 10^[illegible] | 5500000 | 12000 |
| | | MP10G | 3800 L/day | 0.000075 kg/L | 1.99 × 10^[illegible] | 5.58 × 10^[illegible] | 500000 | 1900 |
| | | MP10W | 150 L/day | | 1.55 × 10^[illegible] | 6.56 × 10^[illegible] | 75000000 | 1600000 |
| | | Backpack | | | 7.06 × 10^[illegible] | 8.75 × 10^[illegible] | 13000000 | 1100000 |
| | ML | Aerial - ML | 400 ha/day | 0.0075 kg/ha | 1.92 × 10^[illegible] | 6.00 × 10^[illegible] | 5200000 | 170000 |
| | A | Aerial - A | | | 5.02 × 10^[illegible] | 2.03 × 10^[illegible] | 29000000 | 5800000 |
| Potato | MLA | AirBlast | 20 ha/day | 0.0125 kg/ha | 2.75 × 10^[illegible] | 2.31 × 10^[illegible] | 3600000 | 430000 |
| | | GB Custom | 360 ha/day | | 8.75 × 10^[illegible] | 1.48 × 10^[illegible] | 2100000 | 6900 |
| | | MP10G | 3800 L/day | 0.000065 kg/L | 1.72 × 10^[illegible] | 8.06 × 10^[illegible] | 580000 | 2100 |
| | | MP10W | 150 L/day | | 1.15 × 10^[illegible] | 5.51 × 10^[illegible] | 87000000 | 1800000 |
| | | Backpack | | | 6.68 × 10^[illegible] | 7.57 × 10^[illegible] | 15000000 | 1300000 |
| | ML | Aerial - ML | 400 ha/day | 0.0075 kg/ha | 1.92 × 10^[illegible] | 6.00 × 10^[illegible] | 5200000 | 170000 |

| Crop | Scenario | Application Equipment | ATPD | Max Rate (kg/ha or kg/L) | Dermal Exposure[a] (mg/kg/day) | Inhalation Exposure[b] (mg/kg/day) | MOE | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | Dermal[c] | Inhalation[d] |
| | A | Aerial - A | | | $3.62 \times 10^{-6}$ | $2.63 \times 10^{-6}$ | 2900000 | 380000 |
| Soybean | MLA | Airblast | 20 ha/day | 0.0065 kg/ha | $1.43 \times 10^{-5}$ | $1.20 \times 10^{-5}$ | 700000 | 83000 |
| | | GB Custom | 300 ha/day | | $2.46 \times 10^{-5}$ | $7.49 \times 10^{-5}$ | 410000 | 13000 |
| | | MP/HG | 3800 L/day | 0.000065 kg/L | $1.72 \times 10^{-4}$ | $4.66 \times 10^{-4}$ | 58000 | 2100 |
| | | MP/HW | 150 L/day | | $1.15 \times 10^{-6}$ | $5.51 \times 10^{-6}$ | 8700000 | 180000 |
| | | Backpack | | | $6.64 \times 10^{-6}$ | $7.57 \times 10^{-6}$ | 1500000 | 130000 |
| | ML | Aerial - ML | 400 ha/day | 0.0065 kg/ha | $1.66 \times 10^{-5}$ | $5.20 \times 10^{-5}$ | 600000 | 19000 |
| | A | Aerial - A | | | $3.14 \times 10^{-6}$ | $2.28 \times 10^{-6}$ | 3200000 | 440000 |
| Sunflower | MLA | Airblast | 20 ha/day | 0.005 kg/ha | $1.10 \times 10^{-5}$ | $9.25 \times 10^{-6}$ | 910000 | 110000 |
| | | GB Custom | 300 ha/day | | $1.89 \times 10^{-5}$ | $5.76 \times 10^{-5}$ | 530000 | 17000 |
| | | MP/HG | 3800 L/day | 0.00005 kg/L | $1.33 \times 10^{-4}$ | $3.59 \times 10^{-4}$ | 75000 | 2800 |
| | | MP/HW | 150 L/day | | $8.84 \times 10^{-7}$ | $4.24 \times 10^{-6}$ | 11000000 | 240000 |
| | | Backpack | | | $5.11 \times 10^{-6}$ | $5.82 \times 10^{-6}$ | 2000000 | 170000 |
| | ML | Aerial - ML | 400 ha/day | 0.005 kg/ha | $1.28 \times 10^{-5}$ | $4.00 \times 10^{-5}$ | 780000 | 25000 |
| | A | Aerial - A | | | $2.42 \times 10^{-6}$ | $1.75 \times 10^{-6}$ | 4100000 | 570000 |
| Shelterbelts (incl. Chokecherry) | MLA | Airblast | 20 ha/day | 0.135 kg/ha | $2.97 \times 10^{-4}$ | $2.50 \times 10^{-4}$ | 34000 | 4000 |
| | | GB Farmer/Custom | 26 ha/day | | $3.69 \times 10^{-5}$ | $1.12 \times 10^{-4}$ | 270000 | 8900 |
| | | MP/HG | 3800 L/day | 0.000675 kg/L | $1.79 \times 10^{-3}$ | $4.84 \times 10^{-3}$ | 5600 | 210 |
| | | MP/HW | 150 L/day | | $1.19 \times 10^{-5}$ | $5.72 \times 10^{-5}$ | 840000 | 17000 |
| | | Backpack | | | $6.89 \times 10^{-5}$ | $7.86 \times 10^{-5}$ | 150000 | 13000 |
| | | RO/W Sprayer | 3800 L/day | | $2.96 \times 10^{-4}$ | $2.12 \times 10^{-4}$ | 34000 | 4700 |
| | ML | Aerial - ML | 400 ha/day | 0.0075 kg/ha | $1.92 \times 10^{-5}$ | $6.00 \times 10^{-5}$ | 520000 | 17000 |
| | A | Aerial - A | | | $3.62 \times 10^{-6}$ | $2.63 \times 10^{-6}$ | 2900000 | 380000 |
| Turf (Golf Courses, Residential Lawns, Sod Farms) | MLA | Airblast | 20 ha/day | 0.06 kg/ha | $1.32 \times 10^{-4}$ | $1.11 \times 10^{-4}$ | 76000 | 9000 |
| | | GB Custom | 300 ha/day | | $2.27 \times 10^{-4}$ | $6.91 \times 10^{-4}$ | 44000 | 1400 |
| | | MP/HG | 3800 L/day | 0.0001 kg/L | $2.65 \times 10^{-4}$ | $7.17 \times 10^{-4}$ | 38000 | 1400 |
| | | MP/HW | 150 L/day | | $1.77 \times 10^{-6}$ | $8.48 \times 10^{-6}$ | 5700000 | 120000 |
| | | Backpack | | | $1.02 \times 10^{-5}$ | $1.16 \times 10^{-5}$ | 980000 | 86000 |
| Alfalfa (seed production only), Clover (red, established, for seed production only) | MLA | Airblast | 20 ha/day | 0.0125 kg/ha | $2.75 \times 10^{-5}$ | $2.31 \times 10^{-5}$ | 360000 | 43000 |
| | | GB Custom | 300 ha/day | | $4.73 \times 10^{-5}$ | $1.44 \times 10^{-4}$ | 210000 | 6900 |
| | | MP/HG | 3800 L/day | 0.000125 kg/L | $3.32 \times 10^{-4}$ | $8.97 \times 10^{-4}$ | 30000 | 1100 |

| Crop | Scenario | Application Equipment | ATPD | Max Rate (kg/ha or kg/L) | Dermal Exposure[a] (mg/kg/day) | Inhalation Exposure[b] (mg/kg/day) | MOE | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | Dermal[c] | Inhalation[d] |
| | | MPHW | 150 L/day | | $2.21 \times 10^{-4}$ | $1.06 \times 10^{-5}$ | 4500000 | 94000 |
| | | Backpack | | | $1.28 \times 10^{-3}$ | $1.46 \times 10^{-5}$ | 780000 | 69000 |
| Corn (Field/Seed) | MLA | Airblast | 20 ha/day | 0.015 kg/ha | $3.30 \times 10^{-3}$ | $2.78 \times 10^{-5}$ | 300000 | 36000 |
| | | GB Custom | 360 ha/day | | $5.68 \times 10^{-3}$ | $1.73 \times 10^{-4}$ | 180000 | 5800 |
| | | MPHG | 3800 L/day | 0.000063 kg/L | $1.66 \times 10^{-2}$ | $4.48 \times 10^{-4}$ | 60000 | 2200 |
| | | MPHW | 150 L/day | | $1.11 \times 10^{-4}$ | $5.30 \times 10^{-6}$ | 9000000 | 190000 |
| | | Backpack | | | $6.38 \times 10^{-4}$ | $7.28 \times 10^{-6}$ | 1600000 | 140000 |
| Roadsides | MLA | Airblast | 20 ha/day | 0.0075 kg/ha | $1.65 \times 10^{-3}$ | $1.39 \times 10^{-5}$ | 610000 | 72000 |
| | | GB Custom | 360 ha/day | | $2.84 \times 10^{-3}$ | $8.64 \times 10^{-5}$ | 350000 | 12000 |
| | | MPHG | 3800 L/day | 0.000075 kg/L | $1.99 \times 10^{-2}$ | $5.38 \times 10^{-4}$ | 50000 | 1900 |
| | | MPHW | 150 L/day | | $1.33 \times 10^{-4}$ | $6.36 \times 10^{-6}$ | 7500000 | 160000 |
| | | Backpack | | | $7.66 \times 10^{-4}$ | $8.73 \times 10^{-6}$ | 1300000 | 110000 |
| | | ROW Sprayer | 3800 L/day | | $3.29 \times 10^{-3}$ | $2.35 \times 10^{-5}$ | 300000 | 43000 |
| Apple | MLA | Airblast | 20 ha/day | 0.0125 kg/ha | $2.75 \times 10^{-3}$ | $2.31 \times 10^{-5}$ | 360000 | 43000 |
| | | GB Farmer | 26 ha/day | | $3.42 \times 10^{-4}$ | $1.04 \times 10^{-5}$ | 2900000 | 96000 |
| | | MPHG | 3800 L/day | 0.000004 kg/L | $1.11 \times 10^{-3}$ | $2.99 \times 10^{-5}$ | 900000 | 33000 |
| | | MPHW | 150 L/day | | $7.37 \times 10^{-6}$ | $3.53 \times 10^{-7}$ | 140000000 | 2800000 |
| | | Backpack | | | $4.25 \times 10^{-5}$ | $4.85 \times 10^{-7}$ | 24000000 | 2100000 |
| Asparagus, Onion, Tobacco (Post-planting treatment) | MLA | Airblast | 20 ha/day | 0.01 kg/ha | $2.20 \times 10^{-3}$ | $1.85 \times 10^{-5}$ | 450000 | 54000 |
| | | GB Farmer | 26 ha/day | | $2.73 \times 10^{-4}$ | $8.32 \times 10^{-6}$ | 3700000 | 120000 |
| | | MPHG | 3800 L/day | 0.00005 kg/L | $1.33 \times 10^{-2}$ | $3.59 \times 10^{-4}$ | 75000 | 2800 |
| | | MPHW | 150 L/day | | $8.84 \times 10^{-5}$ | $4.24 \times 10^{-6}$ | 11000000 | 240000 |
| | | Backpack | | | $5.11 \times 10^{-4}$ | $5.82 \times 10^{-6}$ | 2000000 | 170000 |
| Blueberry (high and low bush) | MLA | Airblast | 20 ha/day | 0.0075 kg/ha | $1.65 \times 10^{-3}$ | $1.39 \times 10^{-5}$ | 610000 | 72000 |
| | | GB Farmer | 26 ha/day | | $2.05 \times 10^{-4}$ | $6.24 \times 10^{-6}$ | 4900000 | 160000 |
| | | MPHG | 3800 L/day | 0.000056 kg/L | $1.49 \times 10^{-2}$ | $4.02 \times 10^{-4}$ | 67000 | 2500 |
| | | MPHW | 150 L/day | | $9.91 \times 10^{-5}$ | $4.75 \times 10^{-6}$ | 10000000 | 210000 |
| | | Backpack | | | $5.72 \times 10^{-4}$ | $6.52 \times 10^{-6}$ | 1700000 | 150000 |
| Tomato (field) | MLA | Airblast | 20 ha/day | 0.0075 kg/ha | $1.65 \times 10^{-3}$ | $1.39 \times 10^{-5}$ | 610000 | 72000 |
| | | GB Farmer | 26 ha/day | | $2.05 \times 10^{-4}$ | $6.24 \times 10^{-6}$ | 4900000 | 160000 |
| | | MPHG | 3800 L/day | 0.000065 kg/L | $1.72 \times 10^{-2}$ | $4.66 \times 10^{-4}$ | 58000 | 2100 |
| | | MPHW | 150 L/day | | $1.15 \times 10^{-4}$ | $5.51 \times 10^{-6}$ | 8700000 | 180000 |

| Crop | Scenario | Application Equipment | ATPD | Max Rate (kg/ha or kg/L) | Dermal Exposure[a] (mg/kg/day) | Inhalation Exposure[b] (mg/kg/day) | MOE | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | Dermal[c] | Inhalation[d] |
| | | Backpack | | | $6.64 \times 10^{-4}$ | $7.57 \times 10^{-6}$ | 1500000 | 130000 |
| Broccoli, Brussels Sprouts, Cabbage, Cauliflower | MLA | Airblast | 20 ha/day | 0.01 kg/ha | $2.20 \times 10^{-3}$ | $1.85 \times 10^{-5}$ | 450000 | 54000 |
| | | GB Farmer | 26 ha/day | | $2.73 \times 10^{-4}$ | $8.32 \times 10^{-6}$ | 3700000 | 120000 |
| | | MPHG | 3800 L/day | 0.000065 kg/L | $1.72 \times 10^{-2}$ | $4.66 \times 10^{-4}$ | 58000 | 2100 |
| | | MPHW | 150 L/day | | $1.15 \times 10^{-4}$ | $5.51 \times 10^{-6}$ | 8700000 | 180000 |
| | | Backpack | | | $6.64 \times 10^{-4}$ | $7.57 \times 10^{-6}$ | 1500000 | 130000 |
| Cavolo Broccolo, Chinese Broccoli, Chinese Mustard Cabbage (gai choi), Kohlrabi, Napa Chinese Cabbage | MLA | Airblast | 20 ha/day | 0.0065 kg/ha | $1.43 \times 10^{-3}$ | $1.20 \times 10^{-5}$ | 700000 | 83000 |
| | | GB Farmer | 26 ha/day | | $1.78 \times 10^{-4}$ | $5.41 \times 10^{-6}$ | 5600000 | 180000 |
| | | MPHG | 3800 L/day | 0.000065 kg/L | $1.72 \times 10^{-2}$ | $4.66 \times 10^{-4}$ | 58000 | 2100 |
| | | MPHW | 150 L/day | | $1.15 \times 10^{-4}$ | $5.51 \times 10^{-6}$ | 8700000 | 180000 |
| | | Backpack | | | $6.64 \times 10^{-4}$ | $7.57 \times 10^{-6}$ | 1500000 | 130000 |
| Kale | MLA | Airblast | 20 ha/day | 0.01 kg/ha | $2.20 \times 10^{-3}$ | $1.85 \times 10^{-5}$ | 450000 | 54000 |
| | | GB Farmer | 26 ha/day | | $2.73 \times 10^{-4}$ | $8.32 \times 10^{-6}$ | 3700000 | 120000 |
| | | MPHG | 3800 L/day | 0.000033 kg/L | $8.84 \times 10^{-3}$ | $2.39 \times 10^{-4}$ | 110000 | 4200 |
| | | MPHW | 150 L/day | | $5.90 \times 10^{-5}$ | $2.83 \times 10^{-6}$ | 17000000 | 350000 |
| | | Backpack | | | $3.40 \times 10^{-4}$ | $3.88 \times 10^{-6}$ | 2900000 | 260000 |
| Peach, Strawberry | MLA | Airblast | 20 ha/day | 0.01 kg/ha | $2.20 \times 10^{-3}$ | $1.85 \times 10^{-5}$ | 450000 | 54000 |
| | | GB Farmer | 26 ha/day | | $2.73 \times 10^{-4}$ | $8.32 \times 10^{-6}$ | 3700000 | 120000 |
| | | MPHG | 3800 L/day | 0.000003 kg/L | $8.84 \times 10^{-4}$ | $2.39 \times 10^{-5}$ | 1100000 | 42000 |
| | | MPHW | 150 L/day | | $5.90 \times 10^{-6}$ | $2.83 \times 10^{-7}$ | 170000000 | 3500000 |
| | | Backpack | | | $3.40 \times 10^{-5}$ | $3.88 \times 10^{-7}$ | 29000000 | 2600000 |
| Pear | MLA | Airblast | 20 ha/day | 0.0175 kg/ha | $3.85 \times 10^{-3}$ | $3.24 \times 10^{-5}$ | 260000 | 31000 |
| | | GB Farmer | 26 ha/day | | $4.78 \times 10^{-4}$ | $1.46 \times 10^{-5}$ | 2100000 | 69000 |
| | | MPHG | 3800 L/day | 0.000006 kg/L | $1.55 \times 10^{-3}$ | $4.18 \times 10^{-5}$ | 650000 | 24000 |
| | | MPHW | 150 L/day | | $1.03 \times 10^{-5}$ | $4.94 \times 10^{-7}$ | 97000000 | 2000000 |
| | | Backpack | | | $5.96 \times 10^{-5}$ | $6.79 \times 10^{-7}$ | 17000000 | 1500000 |
| Pepper (field) | MLA | Airblast | 20 ha/day | 0.015 kg/ha | $3.30 \times 10^{-3}$ | $2.78 \times 10^{-5}$ | 300000 | 36000 |
| | | GB Farmer | 26 ha/day | | $4.10 \times 10^{-4}$ | $1.25 \times 10^{-5}$ | 2400000 | 80000 |
| | | MPHG | 3800 L/day | 0.000075 kg/L | $1.99 \times 10^{-2}$ | $5.38 \times 10^{-4}$ | 50000 | 1900 |
| | | MPHW | 150 L/day | | $1.33 \times 10^{-4}$ | $6.36 \times 10^{-6}$ | 7500000 | 160000 |

| Crop | Scenario | Application Equipment | ATPD | Max Rate (kg/ha or kg/L) | Dermal Exposure[a] (mg/kg/day) | Inhalation Exposure[b] (mg/kg/day) | MOE | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | Dermal[c] | Inhalation[d] |
| | | Backpack | | | $7.66 \times 10^{-4}$ | $8.73 \times 10^{-6}$ | 1300000 | 110000 |
| Saskatoon Berry | MLA | Airblast | 20 ha/day | 0.01 kg/ha | $2.20 \times 10^{-3}$ | $1.85 \times 10^{-5}$ | 450000 | 54000 |
| | | GB Farmer | 26 ha/day | | $2.73 \times 10^{-4}$ | $8.32 \times 10^{-6}$ | 3700000 | 120000 |
| | | MPHG | 3800 L/day | 0.000022 kg/L | $5.90 \times 10^{-3}$ | $1.59 \times 10^{-4}$ | 170000 | 6300 |
| | | MPHW | 150 L/day | | $3.93 \times 10^{-5}$ | $1.88 \times 10^{-6}$ | 25000000 | 530000 |
| | | Backpack | | | $2.27 \times 10^{-4}$ | $2.59 \times 10^{-6}$ | 4400000 | 390000 |
| Tobacco (Pre-plant soil treatment) | MLA | Airblast | 20 ha/day | 0.02 kg/ha | $4.40 \times 10^{-3}$ | $3.70 \times 10^{-5}$ | 230000 | 27000 |
| | | GB Farmer | 26 ha/day | | $5.47 \times 10^{-4}$ | $1.66 \times 10^{-5}$ | 1800000 | 60000 |
| | | MPHG | 3800 L/day | 0.0001 kg/L | $2.65 \times 10^{-2}$ | $7.17 \times 10^{-4}$ | 38000 | 1400 |
| | | MPHW | 150 L/day | | $1.77 \times 10^{-4}$ | $8.48 \times 10^{-6}$ | 5700000 | 120000 |
| | | Backpack | | | $1.02 \times 10^{-3}$ | $1.16 \times 10^{-5}$ | 980000 | 86000 |
| Tobacco (Rye or Wheat cover crop) | MLA | Airblast | 20 ha/day | 0.005 kg/ha | $1.10 \times 10^{-3}$ | $9.25 \times 10^{-6}$ | 910000 | 110000 |
| | | GB Farmer | 26 ha/day | | $1.37 \times 10^{-4}$ | $4.16 \times 10^{-6}$ | 7300000 | 240000 |
| | | MPHG | 3800 L/day | 0.000025 kg/L | $6.63 \times 10^{-3}$ | $1.79 \times 10^{-4}$ | 150000 | 5600 |
| | | MPHW | 150 L/day | | $4.42 \times 10^{-5}$ | $2.12 \times 10^{-6}$ | 23000000 | 470000 |
| | | Backpack | | | $2.55 \times 10^{-4}$ | $2.91 \times 10^{-6}$ | 3900000 | 340000 |
| Tobacco (Greenhouse) | MLA | MPHG | 3800 L/day | 0.000013 kg/L | $3.54 \times 10^{-3}$ | $9.56 \times 10^{-5}$ | 280000 | 10000 |
| | | MPHW | 150 L/day | | $2.36 \times 10^{-5}$ | $1.13 \times 10^{-6}$ | 42000000 | 880000 |
| | | Backpack | | | $1.36 \times 10^{-4}$ | $1.55 \times 10^{-6}$ | 7300000 | 640000 |
| Ornamentals (Greenhouse) | MLA | MPHG | 3800 L/day | 0.000025 kg/L | $6.63 \times 10^{-3}$ | $1.79 \times 10^{-4}$ | 150000 | 5600 |
| | | MPHW | 150 L/day | | $4.42 \times 10^{-5}$ | $2.12 \times 10^{-6}$ | 23000000 | 470000 |
| | | Backpack | | | $2.55 \times 10^{-4}$ | $2.91 \times 10^{-6}$ | 3900000 | 340000 |

ATPD = area treated per day, MOE = margin of exposure, M = mixer, L = loader, A = applicator, GB = groundboom, MPHG = mechanically pressurized handgun, MPHW = manually pressurized handwand,

ROW = right-of-way

Shaded cells indicate MOEs that are less than target

Baseline PPE was assumed for all scenarios

[a] Dermal exposure (mg/kg/day) = (dermal unit exposure × ATPD × maximum application rate)/80 kg body weight

[b] Inhalation exposure (mg/kg/day) = (inhalation unit exposure × ATPD × maximum application rate)/80 kg body weight

[c] Based on a dermal NOAEL of 1000 mg/kg/day, target MOE = 1000

[d] Based on an oral LOAEL of 1 mg/kg/day, target MOE = 300

## Table 2 Short-, Intermediate-, and Long-Term Commercial Mixer, Loader, and Applicator Exposure and Risk Assessment with Mitigation

| Crop | Scenario | Application Equipment | ATPD | Max Rate | Dermal Exposure[a] (mg/kg bw/day) | Inhalation Exposure[b] | | MOE | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | w/o resp | w/ resp | Dermal[c] | Inhalation[d] | |
| | | | | | | | | | w/o resp | w/ resp |
| Shelterbelts (incl. chokecherry) | MLA | MPHG | 3800 L/day | 0.000675 L/ha | 0.1791 | $4.84 \times 10^{-3}$ | $4.84 \times 10^{-4}$ | 5600 | 210 | 2100 |

ATPD = area treated per day, MOE = margin of exposure, M = mixer, L = loader, A = applicator, MPHG = mechanically pressurized handgun

Shaded cells indicate MOEs that are less than target

[a] Dermal exposure (mg/kg/day) = (dermal unit exposure × ATPD × maximum application rate)/80 kg body weight

[b] Inhalation exposure (mg/kg/day) = (inhalation unit exposure × ATPD × maximum application rate)/80 kg body weight

[c] Based on a dermal NOAEL of 1000 mg/kg/day, target MOE = 1000

[d] Based on an oral LOAEL of 1 mg/kg/day, target MOE = 300

## Table 3 Postapplication Exposure and Risk Assessment

| Crop | Activity | TC[a] ($cm^2$/hr) | Rate (kg ai/ha) | Number of Applications per year | Interval between Applications (days) | MOE[b] (Day 0) | REI[c,d] |
|---|---|---|---|---|---|---|---|
| Alfalfa (seed production only) | Irrigation (Hand set) | 1750 | 0.0125 | 1 | n/a | 190000 | 12 hours |
| | Scouting | 1100 | | | | 290000 | |
| Apples | Thinning Fruit | 3000 | 0.0125 | 3 | 7 | 62000 | 12 hours |
| | Harvesting (Hand) | 1400 | | | | 130000 | |
| | Pruning (Hand), Scouting, Training | 580 | | | | 320000 | |
| | Transplanting | 230 | | | | 820000 | |
| | Orchard Maintenance, Propping, Weeding (Hand) | 100 | | | | 1900000 | |
| Asparagus | Irrigation (Hand set) | 1750 | 0.01 | 3 | 7 | 130000 | 12 hours |
| | Harvesting | 1100 | | | | 210000 | |
| | Transplanting | 230 | | | | 1000000 | |
| | Scouting | 210 | | | | 1100000 | |
| | Weeding (Hand) | 70 | | | | 3300000 | |
| Barley | Scouting | 1100 | 0.0075 | 3 | 5 | 250000 | 12 hours |
| Blueberry (high bush) | Irrigation (Hand set) | 1750 | 0.0075 | 3 | 5 | 160000 | 12 hours |
| | Harvesting (Hand) | 1400 | | | | 200000 | |
| | Bird Control, Frost Control, Pruning, Scouting, Weeding (Hand) | 640 | | | | 430000 | |
| | Transplanting | 230 | | | | 1200000 | |
| Blueberry (low bush) | Irrigation (Hand set) | 1750 | 0.0075 | 3 | 5 | 160000 | 12 hours |
| | Scouting, Harvesting (Hand), Transplanting | 1100 | | | | 250000 | |
| | Weeding (Hand) | 70 | | | | 3900000 | |
| Broccoli | Harvesting (Hand) | 5150 | 0.01 | 8 | 10 | 51000 | 12 hours |
| | Weeding (Hand) | 4400 | | | | 59000 | |
| | Scouting (Full foliage) | 4000 | | | | 65000 | |
| | Irrigation (Hand set) | 1750 | | | | 150000 | |
| | Thinning | 1300 | | | | 200000 | |
| | Transplanting | 230 | | | | 1100000 | |
| Brussels Sprouts | Harvesting (Hand) | 5150 | 0.01 | 8 | 10 | 51000 | 12 hours |
| | Weeding (Hand) | 4400 | | | | 59000 | |
| | Scouting (Full foliage), Topping | 4000 | | | | 65000 | |
| | Irrigation (Hand set) | 1750 | | | | 150000 | |

| Crop | Activity | TC[a] (cm²/hr) | Rate (kg ai/ha) | Number of Applications per year | Interval between Applications (days) | MOE[b] (Day 0) | REI[c,d] |
|---|---|---|---|---|---|---|---|
|  | Transplanting | 230 |  |  |  | 1100000 |  |
| Cabbage | Weeding (Hand) | 4400 | 0.01 | 8 | 10 | 59000 | 12 hours |
|  | Irrigation (Hand set) | 1750 |  |  |  | 150000 |  |
|  | Harvesting (Hand and mechanically-assisted), Scouting, Thinning | 1300 |  |  |  | 200000 |  |
|  | Transplanting | 230 |  |  |  | 1100000 |  |
| Canola | Scouting | 1100 | 0.01 | 1 | n/a | 360000 | 12 hours |
| Cauliflower | Harvesting (Hand) | 5150 | 0.01 | 8 | 10 | 51000 | 12 hours |
|  | Weeding (Hand) | 4400 |  |  |  | 59000 |  |
|  | Scouting (Full foliage), Tying/Training | 4000 |  |  |  | 65000 |  |
|  | Irrigation (Hand set) | 1750 |  |  |  | 150000 |  |
|  | Thinning | 1300 |  |  |  | 200000 |  |
|  | Transplanting | 230 |  |  |  | 1100000 |  |
| Cavolo Broccolo, Chinese Broccoli, Chinese Mustard Cabbage (gai choy) | Weeding (Hand) | 4400 | 0.0065 | 3 | 5 | 72000 | 12 hours |
|  | Irrigation (Hand set) | 1750 |  |  |  | 180000 |  |
|  | Harvesting (Hand), Scouting, Thinning | 1300 |  |  |  | 240000 |  |
|  | Transplanting | 230 |  |  |  | 1400000 |  |
| Clover (red, established) | Irrigation (Hand set) | 1750 | 0.0125 | 2 | 14 | 150000 | 12 hours |
|  | Scouting | 1100 |  |  |  | 240000 |  |
| Corn (Field) | Irrigation (Hand set) | 1750 | 0.015 | 3 | 5 | 79000 | 12 hours |
|  | Scouting | 1100 |  |  |  | 130000 |  |
|  | Weeding (Hand) | 70 |  |  |  | 2000000 |  |
| Corn (Seed) | Detasseling (Hand) | 16000 | 0.015 | 3 | 5 | 8600 | 12 hours |
|  | Irrigation (Hand set) | 1750 |  |  |  | 79000 |  |
|  | Scouting | 1100 |  |  |  | 130000 |  |
|  | Weeding (Hand) | 70 |  |  |  | 2000000 |  |
| Corn (Sweet) | Detasseling (Hand) | 16000 | 0.015 | 2 | 5 | 10000 | 12 hours |
|  | Irrigation (Hand set) | 1750 |  |  |  | 96000 |  |
|  | Scouting | 1100 |  |  |  | 150000 |  |
|  | Weeding (Hand) | 70 |  |  |  | 2400000 |  |
| Flax | Scouting | 1100 | 0.0075 | 3 | 5 | 250000 | 12 hours |
| Kale | Irrigation (Hand set) | 1750 | 0.01 | 8 | 10 | 150000 | 12 hours |
|  | Harvesting (Hand) | 1100 |  |  |  | 240000 |  |
|  | Transplanting | 230 |  |  |  | 1100000 |  |
|  | Scouting | 210 |  |  |  | 1200000 |  |
|  | Thinning, Weeding (Hand) | 70 |  |  |  | 3700000 |  |
| Kohlrabi | Harvesting (Hand) | 5150 | 0.0065 | 3 | 5 | 62000 | 12 hours |
|  | Weeding (Hand) | 4400 |  |  |  | 72000 |  |
|  | Scouting, Topping | 4000 |  |  |  | 79000 |  |
|  | Irrigation (Hand set) | 1750 |  |  |  | 180000 |  |
|  | Transplanting | 230 |  |  |  | 1400000 |  |
| Lentil | Scouting | 1100 | 0.0075 | 3 | 5 | 250000 | 12 hours |
|  | Weeding (Hand) | 70 |  |  |  | 3900000 |  |
| Mustard (& Oilseed) | Irrigation (Hand set) | 1750 | 0.01 | 1 | n/a | 230000 | 12 hours |
|  | Harvesting (Hand) | 1100 |  |  |  | 360000 |  |
|  | Transplanting | 230 |  |  |  | 1700000 |  |
|  | Scouting | 210 |  |  |  | 1900000 |  |
|  | Thinning, Weeding (Hand) | 70 |  |  |  | 5700000 |  |
| Napa Chinese Cabbage | Weeding (Hand) | 4400 | 0.0065 | 3 | 5 | 72000 | 12 hours |
|  | Irrigation (Hand set) | 1750 |  |  |  | 180000 |  |
|  | Harvesting (Hand), Scouting, Thinning | 1300 |  |  |  | 240000 |  |
|  | Transplanting | 230 |  |  |  | 1400000 |  |

| Crop | Activity | TC^a (cm²/hr) | Rate (kg ai/ha) | Number of Applications per year | Interval between Applications (days) | MOE^b (Day 0) | REI^c,d |
|---|---|---|---|---|---|---|---|
| Oats | Scouting | 1100 | 0.0075 | 3 | 5 | 250000 | 12 hours |
| | Weeding (Hand) | 70 | | | | 3900000 | |
| Onion | Weeding (Hand) | 4400 | 0.01 | 1 | n/a | 91000 | 12 hours |
| | Irrigation (Hand set) | 1750 | | | | 230000 | |
| | Scouting, Thinning, Harvesting (Hand) | 1300 | | | | 310000 | |
| Pastures, Rangeland, Roadside | Scouting | 1100 | 0.0075 | 3 | 5 | 250000 | 12 hours |
| Peach | Thinning Fruit | 3000 | 0.01 | 1 | n/a | 130000 | 12 hours |
| | Harvesting (Hand) | 1400 | | | | 290000 | |
| | Pruning (Hand), Scouting, Training | 580 | | | | 690000 | |
| | Transplanting | 230 | | | | 1700000 | |
| | Orchard Maintenance, Propping, Weeding (Hand) | 100 | | | | 4000000 | |
| Pear | Thinning Fruit | 3000 | 0.0175 | 3 | 12 | 56000 | 12 hours |
| | Harvesting (Hand) | 1400 | | | | 120000 | |
| | Pruning (Hand), Scouting, Training | 580 | | | | 290000 | |
| | Transplanting | 230 | | | | 730000 | |
| | Orchard Maintenance, Propping, Weeding (Hand) | 100 | | | | 1700000 | |
| Pepper (field) | Irrigation (Hand set) | 1750 | 0.015 | 3 | 5 | 79000 | 12 hours |
| | Harvesting (Hand), Tying/Training | 1100 | | | | 130000 | |
| | Transplanting | 230 | | | | 600000 | |
| | Scouting | 210 | | | | 650000 | |
| | Pruning (Hand), Weeding (Hand) | 70 | | | | 2000000 | |
| Potato | Irrigation (Hand set) | 1750 | 0.0125 | 3 | 5 | 81000 | 12 hours |
| | Roguing | 1000 | | | | 140000 | |
| | Scouting | 210 | | | | 670000 | |
| | Weeding (Hand) | 70 | | | | 2000000 | |
| Saskatoon Berry | Irrigation (Hand set) | 1750 | 0.01 | 3 | 7 | 120000 | 12 hours |
| | Harvesting (Hand) | 1400 | | | | 150000 | |
| | Bird/Frost Control, Pruning (Hand), Scouting, Weeding (Hand) | 640 | | | | 320000 | |
| | Transplanting | 230 | | | | 900000 | |
| Shelterbelt (incl. Chokecherry) | Scouting | 500 | 0.135 | 1 | n/a | 39000 | 12 hours |
| Soybean | Scouting | 1100 | 0.0065 | 3 | 5 | 290000 | 12 hours |
| | Weeding (Hand) | 70 | | | | 4500000 | |
| Strawberry | Harvesting (Hand) | 1100 | 0.01 | 2 | 7 | 250000 | 12 hours |
| | Transplanting | 230 | | | | 1100000 | |
| | Scouting | 210 | | | | 1200000 | |
| | Canopy Management, Weeding (Hand) | 70 | | | | 3600000 | |
| Sugarbeet | Harvesting (Hand) | 1100 | 0.01 | 1 | n/a | 360000 | 12 hours |
| | Scouting | 210 | | | | 1900000 | |
| | Thinning, Weeding (Hand) | 70 | | | | 5700000 | |
| Sunflower | Scouting | 90 | 0.005 | 1 | n/a | 8900000 | 12 hours |
| Tobacco (Post-Planting Treatment) | Irrigation (Hand set) | 1750 | 0.01 | 1 | n/a | 230000 | 12 hours |
| | Canopy Management, Harvesting | 800 | | | | 500000 | |
| | Transplanting | 230 | | | | 1700000 | |

| Crop | Activity | TC[a] (cm²/hr) | Rate (kg ai/ha) | Number of Applications per year | Interval between Applications (days) | MOE[b] (Day 0) | REI[c,d] |
|---|---|---|---|---|---|---|---|
| | Scouting, Weeding (Hand) | 90 | | | | 4400000 | |
| Tobacco (Pre-Plant Soil Treatment) | Irrigation (Hand set) | 1750 | 0.02 | 1 | n/a | 110000 | 12 hours |
| | Canopy Management, Harvesting | 800 | | | | 250000 | |
| | Transplanting | 230 | | | | 870000 | |
| | Scouting, Weeding (Hand) | 90 | | | | 2200000 | |
| Tobacco (Wheat/Rye Cover Crop) | Irrigation (Hand set) | 1750 | 0.005 | 1 | n/a | 460000 | 12 hours |
| | Canopy Management, Harvesting | 800 | | | | 5500000 | |
| | Transplanting | 230 | | | | 3000000 | |
| | Scouting, Weeding (Hand) | 90 | | | | 8000000 | |
| Tomato (field) | Irrigation (Hand set) | 1750 | 0.0075 | 3 | 5 | 160000 | 12 hours |
| | Harvesting (Hand), Tying/Training | 1100 | | | | 250000 | |
| | Transplanting | 230 | | | | 1200000 | |
| | Scouting | 210 | | | | 1300000 | |
| | Pruning (Hand), Weeding (Hand) | 70 | | | | 3900000 | |
| Turf (Golf Courses, Residential Lawns, Sod Farms) | Transplanting/Planting, Harvesting | 6700 | 0.06 | 2 | 14 | 200000 | 12 hours |
| | Cup Changing, Irrigation Repair, Miscellaneous Grooming, Mowing, Watering | 3500 | | | | 390000 | |
| | Aerating, Fertilizing, Pruning (Hand), Weeding (Mechanical), Scouting, Seeding | 1000 | | | | 1400000 | |
| Wheat | Scouting | 1100 | 0.0075 | 3 | 5 | 250000 | 12 hours |
| | Weeding (Hand) | 70 | | | | 3900000 | |
| **Greenhouse Crops[e]** | | | | | | | |
| Tobacco | Irrigation (Hand set) | 1750 | 0.02 | 3 | 5 | 58000 | 12 hours |
| | All other activities | 230 | | | | 290000 | |
| Ornamentals | Irrigation (Hand set) | 1750 | 0.023 | 3 | 5 | 50000 | 12 hours |
| | All other activities | 230 | | | | 250000 | |

USC = use site category, REI = restricted-entry interval, MOE = margin of exposure

[a] TC = transfer coefficient

[b] Based on a dermal NOAEL of 1000 mg/kg bw/day and a target MOE of 1000

[c] If the target MOE is met, the REI is set at 12 hours

[d] Since no DFR studies were available or submitted, a peak default DFR value of 25% of the application rate was used (with 10% dissipation)

[e] Peak default DFR value of 25% of the application rate was used with the assumption of no dissipation

# Appendix V Non-Occupational Postapplication Risk Assessment

## Table 1 Residential Postapplication Dermal Exposure

| Lifestage | TTR (µg/cm²) | TC[a] (cm²/hr) | Hours of Exposure (hours) | Dermal Exposure[b] (mg/kg bw/day) | Dermal MOE[c] |
|---|---|---|---|---|---|
| **High Contact Lawn Activities** | | | | | |
| Adult | 0.0074 | 180,000 | 1.5 | 0.0249 | 40000 |
| Youth | | 148,000 | 1.5 | 0.0249 | 40000 |
| Children (1 to < 2) | | 49,000 | 1.5 | 0.0495 | 20000 |
| **Mowing Turf** | | | | | |
| Adult | 0.0074 | 5,500 | 1 | 0.0005 | 1970000 |
| Youth | | 4,500 | | 0.0006 | 1720000 |
| **Golfing** | | | | | |
| Adult | 0.0074 | 5,300 | 4 | 0.0020 | 510000 |
| Youth | | 4,400 | | 0.0023 | 440000 |
| Children (6 to < 11) | | 2,900 | | 0.0027 | 370000 |

TTR = turf transferable residue; TC = transfer coefficient

[a] Transfer coefficients are based on the USEPA Residential SOPs (USEPA, 2012)

[b] Dermal Exposure = (TTR (µg/cm²) × TC (cm²/hr) × Duration)/BW (kg)

[c] Adult, youth and children short- to intermediate-term MOEs are based on a dermal NOAEL of 1000 mg/kg bw/day with a target MOE of 1000.

## Table 2 Residential Postapplication Incidental Oral Exposure: Hand-to-Mouth

| Lifestage | Hand Residue[a] (mg/cm²) | Exposure Time (hours/day) | HtM events per hour | Oral Dose[b] (mg/kg/day) | MOE[c] |
|---|---|---|---|---|---|
| 1 to < 2 years | 0.00011 | 1.5 | 13.9 | 0.0010 | 990 |

HtM = hand to mouth

[a] Fraction of residue on the hands (mg/cm²) is the residue available for transfer (based on 2 applications, 14 day interval)

[b] Where: Absorbed Dose (mg/kg/day) = [(Hand Residue (mg/cm²) × (Fraction of hand mouthed/event (0.06) × Surface Area of one hand (150 cm²)) × (Exposure Time (hr) × Replenishment Intervals (4/hr)) × (1 − (1 − Saliva Extraction Factor (0.48))$^{\text{Number of events per hour (13.9)/Replenishment intervals (4/hr)}}$)]/ Body Weight (11 kg)

[c] MOE = margin of exposure; MOE was based on an oral LOAEL of 1 mg/kg bw/day with a target of 300

## Table 3 Residential Postapplication Incidental Oral Exposure: Object-to-Mouth

| Lifestage | Object Residue[a] (µg/cm²) | Exposure Time (hours/day) | OtM events per hour | Oral Dose[b] (mg/kg/day) | MOE[c] |
|---|---|---|---|---|---|
| Children (1 to < 2) | 0.00737 | 1.5 | 8.8 | $3.0 \times 10^{-5}$ | 32600 |

OtM = object to mouth

[a] Where Object Residue (µg/cm²) = Residue Available for Transfer (µg/cm²) × Fraction of Residue Transferred (based on 2 applications, 14 day interval)

[b] Where: Absorbed Dose (mg/kg bw/day) = [(Object Residue (µg/cm²) × 0.001 mg/µg × Surface Area Object Mouthed (10 cm²/event)) × (Exposure Time (hr/day) × Replenishment Intervals (4/hr)) × (1 − (1 − Saliva Extraction (0.48))$^{\text{Number of object-to-mouth events (8.8)/Replenishment intervals (4/hr)}}$)]/ Body weight (11 kg)

[c] MOE = margin of exposure; MOE was based on an oral LOAEL of 1 mg/kg bw/day with a target of 300

### Table 4 Residential Postapplication Incidental Oral Exposure: Incidental Soil Ingestion

| Lifestage | SR_t (µg/g)[a] | Ingestion Rate (IgR) mg/day | Oral Dose[b] (mg/kg bw/day) | MOE[c] |
|---|---|---|---|---|
| 1 to < 2 years | 0.402 | 50 | $1.8 \times 10^{-6}$ | 547000 |

[a] $SR_t$ = Soil residue (µg/g) on day 0

[b] Where Absorbed Dose (mg/kg bw/day) = [(Object Residue (µg/cm$^2$) × 0.001 mg/µg × Surface Area Object Mouthed (10 cm$^2$/event)) × (Exposure Time (hr/day) ÷ Replenishment Intervals (4/hr)) × (1 − (1 − Saliva Extraction (0.48))$^{[illegible]}$)] / Body weight (11 kg)

[c] MOE = margin of exposure. For children short-term MOE was based on an oral LOAEL of 1 mg/kg bw/day with a target of 300

### Table 5 Bystander Exposure and Risk Assessment

| Crop | Activity | TC[a] (cm$^2$/hr) | Rate (kg ai/ha) | Dermal Exposure[b] (mg/kg bw/day) | MOE[c] (Day 0) |
|---|---|---|---|---|---|
| Pastures, Rangeland and Roadsides[d] | Hiker – Adult | 580 | 0.0675 | 0.5272 | 1900000 |
| | Hiker – Youth | 476 | | 0.6068 | 1650000 |
| | Hiker – Child (6 to < 11) | 319 | | 0.7249 | 1380000 |

[a] TC = transfer coefficient. Value is based on scouting in an orchard.

[b] Since no DFR studies were submitted, a peak default DFR value of 25% of the application rate was used.

[c] Based on a dermal NOAEL of 1000 mg/kg bw/day and a target MOE of 1000.

[d] Based on 5 applications per year with a 7 day interval.

# Appendix VI Dietary Exposure and Risk Estimates for Deltamethrin

## Table 1 Acute Dietary Exposure and Risk Estimates for Deltamethrin

| | Acute exposure (95th percentile) | | | |
|---|---|---|---|---|
| | Food only | | Food + water | |
| | Exposure (mg/kg bw/day) | %ARfD | Exposure (mg/kg bw/day) | %ARfD |
| General Population: | 0.001033 | 34.43 | 0.001034 | 34.5 |
| Infants (< 1 year old): | 0.001509 | 50.29 | 0.001526 | 50.9 |
| Children 1-2 years old | 0.001985 | 66.17 | 0.001990 | 66.3 |
| Children 3-5 years old | 0.001648 | 54.93 | 0.001650 | 55.0 |
| Children 6-12 years old | 0.001149 | 38.29 | 0.001146 | 38.2 |
| Youth 13-19 years old | 0.000827 | 27.58 | 0.000839 | 28.0 |
| Adults 20-49 years old | 0.000718 | 23.95 | 0.000723 | 24.1 |
| Adults 50+ years old | 0.000578 | 19.26 | 0.000584 | 19.5 |
| Females 13-49 years old | 0.000693 | 23.09 | 0.000697 | 23.2 |

## Table 2 Chronic Dietary Exposure and Risk Estimates for Deltamethrin

| | Chronic exposure | | | |
|---|---|---|---|---|
| | Food only | | Food + water | |
| | Exposure (mg/kg bw/day) | %ADI | Exposure (mg/kg bw/day) | %ADI |
| General Population: | 0.000317 | 10.6 | 0.000321 | 10.7 |
| Infants (<1 year old) | 0.000462 | 15.4 | 0.000476 | 15.9 |
| Children 1-2 years old | 0.000861 | 28.7 | 0.000867 | 28.9 |
| Children 3-5 years old | 0.000737 | 24.6 | 0.000743 | 24.8 |
| Children 6-12 years old | 0.000497 | 16.6 | 0.000501 | 16.7 |
| Youth 13-19 years old | 0.000312 | 10.4 | 0.000315 | 10.5 |
| Adults 20-49 years old | 0.000252 | 8.4 | 0.000256 | 8.5 |
| Adults 50+ years old | 0.000207 | 6.9 | 0.000211 | 7.0 |
| Females 13-49 years old | 0.000248 | 8.3 | 0.000251 | 8.4 |

Note: ADI and ARfD = 0.003 mg/kg bw/day

# Appendix VII Food Residue Chemistry Summary

## 1.1 Metabolism

Deltamethrin is a pyrethroid pesticide, a synthetic analogue of the natural occurring insecticidal pyrethrins. The pyrethroids are non-systemic (in plants) and are contact and stomach poisons in insects, having an anti-feeding action. Their action occurs on the central and peripheral nervous system on the sodium channels with the lipophilic environment of the membranes at the $Na^+$ gate proteins and they act by modulating the opening and closing of the channels, leading to repetitive synaptic discharge, depolarization and ultimately death.

The metabolism of the pyrethroids is based mainly on the hydrolysis of the ester bond. The resulting cyclopropane carboxylic acid and benzaldehyde moieties are further metabolized by oxidation and conjugation. Some moieties of the intact pyrethroids may be transformed by hydroxylation. Figure 1 describes the metabolic transformations of deltamethrin.

The metabolism of tralomethrin, another pyrethroid insecticide, was investigated in rat and ruminant metabolism studies. It was determined that the biotransformation of tralomethrin starts with a rapid debromination to form deltamethrin. Further transformations follow the same route as the deltamethrin metabolism. Therefore, the use of tralomethrin in the studies is considered to be equivalent to the use of deltamethrin for the purposes of elucidating the nature and the magnitude of the residues for deltamethrin.

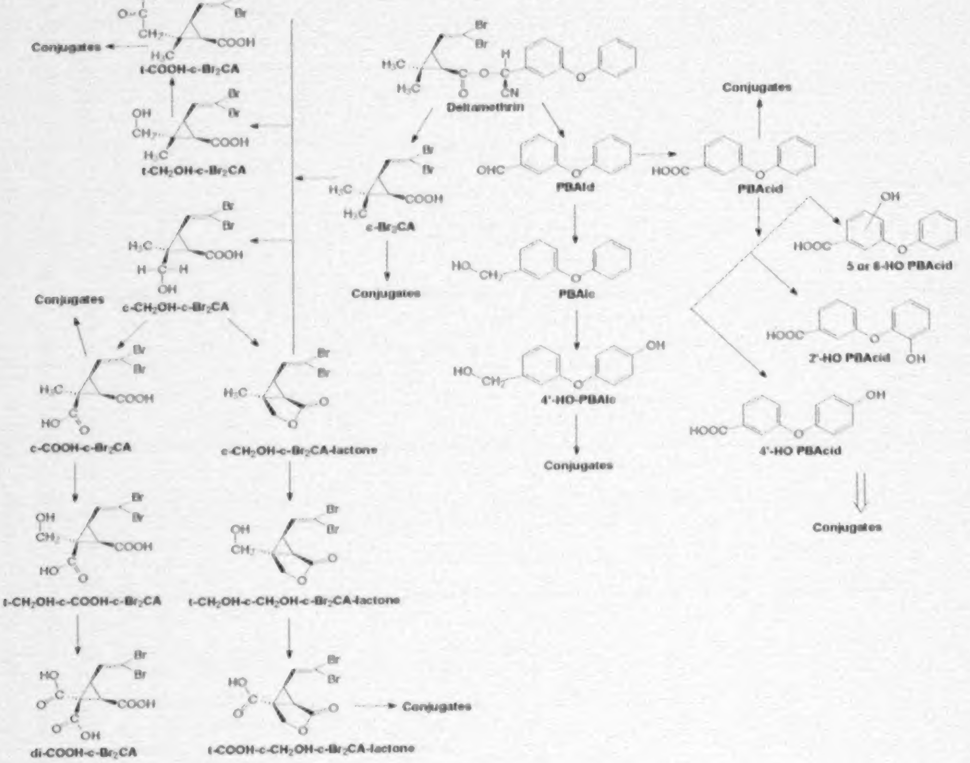
Conjugates
t-COOH-c-Br$_2$CA
t-CH$_2$OH-c-Br$_2$CA
Deltamethrin
c-Br$_2$CA
Conjugates
c-CH$_2$OH-c-Br$_2$CA
Conjugates
c-COOH-c-Br$_2$CA
c-CH$_2$OH-c-Br$_2$CA-lactone
t-CH$_2$OH-c-COOH-c-Br$_2$CA
t-CH$_2$OH-c-CH$_2$OH-c-Br$_2$CA-lactone
di-COOH-c-Br$_2$CA
t-COOH-c-CH$_2$OH-c-Br$_2$CA-lactone
Conjugates
PBAld
PBAcid
Conjugates
PBAlc
4'-HO-PBAlc
Conjugates
5 or 6-HO PBAcid
2'-HO PBAcid
4'-HO PBAcid
Conjugates

Figure 1. Metabolic transformations of deltamethrin

### 1.1.1 Plant metabolism

The nature of deltamethrin residues in the registered crops is adequately understood based on the submitted deltamethrin metabolism studies in apples, beans, corn, cotton and tomatoes. In each of these studies, the three deltamethrin isomers (*cis*-, *trans*- and αR-) are the major $^{14}C$-residues with *cis*-deltamethrin being consistently the major component. All other metabolites were present at < 10% of the total radioactive residues (TRRs) or accounted for < 0.01 ppm.

In plants, *cis*-deltamethrin undergoes isomerization to form *trans*- and αR-deltamethrin. Each of these isomers can undergo cleavage at the ester linkage to yield 3-phenoxybenzaldehyde and *cis*- or *trans*-$Br_2CA$ metabolites that can be further oxidized, reduced, and/or conjugated. Deltamethrin is also directly hydroxylated to 4' hydroxy-deltamethrin or the nitrile group can be hydrolyzed to form an amide metabolite.

**Apples**

The TRRs in the apple rinses decreased with time, whereas the TRRs in apples increased with time. For the rinses from the [$^{14}C$-gem-dimethyl]-label derived samples, TRRs decreased with time from 0.053 ppm at the first harvest rinse, to 0.022 ppm at the second harvest rinse, and to 0.019 ppm at the final harvest. A similar trend was noted for the [$^{14}C$-benzyl]-label derived rinses, with TRRs decreasing from 0.088 ppm at the first harvest, to 0.012 ppm for the second harvest, and to 0.012 ppm again for the third harvest. In apples, for the [$^{14}C$-dimethyl]-label derived samples, TRRs ranged from 0.072 ppm at the first harvest to 0.140 ppm for the second harvest, and to 0.329 ppm for the final harvest samples. For the [$^{14}C$-benzyl]-label derived samples, values ranged from 0.205 ppm for the first harvest, to 0.127 ppm for the second harvest, and finally to 0.458 ppm for the third harvest samples. The majority of the radiocarbon, especially at the later harvest points was associated with the apples rather than the rinses. TRRs were similar between the two radiolabels.

In contrast to the TRRs in the rinses, in apple extracts the TRRs increased with time to a total of 55.8-88.8% of the TRRs identified in apples from each interval. The extractability of the radiocarbon was generally good, and analysis indicated deltamethrin to again be the major component in all extracts. Several minor (< 0.01 ppm) components were noted including 4'-hydroxy-deltamethrin, and the ester cleavage products *cis*- and *trans*-$Br_2CA$, 3-PBAcid, 3-PBAld, 3- PBAlc and 4' HO-PBAlc.

Analysis of deltamethrin for isomer distribution indicated the formation of the *trans*- and αR-isomers. This is consistent with the known propensity for deltamethrin to undergo both chemical and photochemical isomerization. The proposed degradation pathways consist of isomerization, hydrolysis, ester cleavage, reduction, oxidation and hydroxylation.

**Bean**

Methyl-labeled or benzyl-labeled deltamethrin in acetone was injected into the stem of the bean. Ten days after treatment, the plants were harvested and sectioned into shoots and roots.

The bean plants contained approximately 35% and 85% of the $^{14}C$ applied for methyl- and benzyl-labeled deltamethrin, respectively. The remaining radioactivity appeared to have been lost from the plants due to evaporation and/or transpiration. There appeared to be very little translocation of $^{14}C$-residues into the root tissues. Bound $^{14}C$-residues remaining in the solid material from shoots after solvent extraction amounted to 3% (methyl label) and 10% (benzyl label) of the $^{14}C$ applied.

The identity of some but not all of the bound residues in bean plants treated with $^{14}C$-deltamethrin was reported. Only one-third of the bound $^{14}C$-residues were identified, apparently due to the loss of the material in extensive TLC procedures and poor recoveries resulting from the absorption to glass surfaces. Overall, treatment of bean plants with deltamethrin resulted in the formation of a small quantity of unextractable residues present in the form of deltamethrin itself and the PBacid and HO-PBacid metabolites, as well as unidentified polar metabolites present in the form of bound residues.

## Corn

The TRR levels of samples from three harvests were highest in forage (ranged from 3.4 ppm to 4.7 ppm for both labels), foliage (22.4 ppm for $^{14}C$-acid label and 24.2 ppm for $^{14}C$-acid label) and husk (8.8 ppm for $^{14}C$-acid label and 22.6 ppm for $^{14}C$-alcohol label), much lower in cob (0.006 ppm for $^{14}C$-acid label and 0.019 ppm for $^{14}C$-alcohol label) and grain (0.007ppm for $^{14}C$-acid label and 0.058 ppm for $^{14}C$-alcohol label).

The total extractable residues ranged from 87.7% to 113.9% of the TRRs for both labels in all matrices. Deltamethrin ($\alpha R$, $\alpha S$ and *trans* deltamethrin) was detected as the major metabolite with $\alpha S$-deltamethrin accounting for approximately 41% to 70% of all isomers determined by HPLC. Minor metabolites identified (< 10% of the TRRs or < 0.05 ppm) were 3-phenoxybenzoic aldehyde, 3-phenoxybenzoic acid, *trans*-dibromocarboxylic acid, *cis*-dibromocarboxylic acid, 4'-hydroxy deltamethrin, 3-phenoxybenzoic alcohol, 3-(4-hydroxyphenoxy)-benzyl alcohol and amide.

The metabolic pathways involve the cleavage of the cyclopropane ring, benzyl oxygen linkage or ester leading to the formation of trans-isomers, the acrylate, the cyanohydrin, the aldehyde, and the dibromo acid.

## Cotton

The total extractable residues in the benzyl and gem-dimethyl label cotton matrices ranged from 71.2-97.7% of the TRRs (0.034-12.818 ppm), while the final unextractable residues accounted for 2.01-2.72% of the TRRs (0.006-0.0536 ppm). In seeds, deltamethrin (sum of *cis*, *trans* and $\alpha$R) were the major residues in both radiolabeled studies (39.7-42.9% of the TRRs; 0.021-0.023 ppm), with $Br_2CA$ as a minor metabolite at 3.2% of the TRRs (0.0013 ppm) in the gem-dimethyl label only.

In the 4-day and 10-day leaf samples, deltamethrin was the predominant isomer identified (38.4-61.0% of the TRRs; 2.761-8.263 ppm), along with *trans*-deltamethrin (7.2-15.3% of the TRRs; 0.931-1.143 ppm) and αR-deltamethrin (12.2-22.5% of the TRRs; 0.884-3.068 ppm). Approximately 2.6-52.7% of the TRRs were characterized in leaves and seeds (0.008-2.274 ppm).

The metabolic pathway of deltamethrin involves the isomerization of *cis* to αR-deltamethrin and *trans*-deltamethrin. Hydrolysis of the deltamethrin ester bond occurs, resulting in the formation and conjugation of mPBAcid, mPBAlc and $Br_2CA$ (low levels).

**Tomato**

Two trials were performed. In the first one a spray application was performed on the tomato plant whereas in the second, deltamethrin was applied individually to the surface of each tomato fruit.

In tomato samples from the spray study at a pre-harvest interval (PHI) of 28 days, a total of 93.1% of the TRRs ($^{14}C$-gem-dimethyl deltamethrin) were extracted in the organic phase (0.023 ppm); with 94.3% (87.8% of the TRRs) was identified as deltamethrin and 5.7% (5.3% of the TRRs) remaining at the origin of TLC. In the $^{14}C$-benzyl deltamethrin treated tomatoes, a total of 78.3% of the TRRs were extracted in the organic phase (0.018 ppm); 98.4% (77.0% of the TRRs) of which was identified as deltamethrin. 3-phenoxy benzamide or 3-phenoxy benzoic acid was identified at 0.4% of the TRRs in organic extract of tomatoes.

In tomato samples from the surface application study at a PHI of 28 days, a total of 118.2% of the TRRs ($^{14}C$-benzyl deltamethrin) were extracted in the organic phase (0.12 ppm); 100% of which was identified as deltamethrin. In the $^{14}C$-gem-dimethyl deltamethrin treated tomatoes, a total of 79.8% of the TRRs were extracted in the organic phase (0.18 ppm) and 99.9% of which was identified as deltamethrin. Residues of deltamethrin were approximately 0.2 ppm and did not appreciably dissipate during a 28-day period (14 to 28 days) for both radiolabeled deltamethrin. Considering the radioactivity recovery from the treated tomatoes was nearly 100% and no radioactivity observed in vines harvested at both PHIs of 14 and 28 days, it was concluded that no translocation of radioactivity occurred from fruit to the vines.

The proposed metabolic pathways of deltamethrin involve the hydrolysis and conjugation of deltamethrin, and further reduction process resulted in the formation of 3-phenoxybenzoic acid, 3-phenoxy benzamide, 3-phenoxybenzoic alcohol, amide and other minor compounds.

### 1.1.2 Plant metabolism

Three wheat metabolism studies are on file with the PMRA. In the studies, radio-labeled tralkoxydim was applied to wheat at 1.3 to 1.75 times label rates. The pre-harvest intervals (PHIs) ranged from 16 to 100 days for forage and straw samples and 92 to 100 days for grain samples. Tralkoxydim equivalent residues were primarily distributed in straw and forage parts of the plant as residue concentrations in grain samples (0.005-0.02 ppm) were at least 5x lower than concentrations in straw and forage samples (0.10-2.06 ppm). The major residue component found in forage and straw was 2,6-dimethyl-4-(2-ethyl-4,5,6,7-tetrahydro-benzoxazol-4-one) benzyl alcohol, which accounted for approximately 10-20% of the total radioactive residue

(TRR) in those matrices. Several other metabolites (at least 5) were also identified at amounts that were generally below 10% of the TRR. The parent, tralkoxydim was not detected in any of the straw and forage samples indicating that it was extensively metabolized. The metabolic profile of tralkoxydim in grain could not be characterized in any of the studies due to low total residue content.

Based on the data available, residues of tralkoxydim and its related metabolites are expected to occur in low amounts in cereal grains. Thus, the residue definition in cereal commodities is the parent, tralkoxydim.

### 1.1.3 Animal metabolism

The qualitative nature of the deltamethrin residues in livestock has been studied and is understood. Most metabolism studies were conducted by oral administration of radiolabeled deltamethrin or tralomethrin. One cattle study submitted was realized as a dermal application of deltamethrin

The basic metabolic reactions involve cleavage of the ester bond by oxidation and/or hydrolysis, followed by oxidation of the released acid and alcohol moieties. The acid moiety (Br2CA) is transformed into conjugates, chiefly the glucuronide, and excreted in urine. It can also be hydroxylated at one of the *gem*-methyl groups, which is in turn conjugated and excreted. The unstable alcohol moiety is transformed via the aldehyde into the acid (*m*PB acid), which undergoes further oxidation by hydroxylation on aromatic rings and then is extensively excreted in urine, mainly as the 4OH sulfate conjugate.

#### Ruminant

Three deltamethrin metabolism studies were performed on two lactating cows by oral administration and one supplemental study by dermal application.

In the **first study** 100 mg/kg bw of $^{14}C$ labeled (gem-dimethyl or benzyl) deltamethrin were fed to lactating dairy cows for three consecutive days. Residues were determined in samples obtained by slaughtering the animals 24 hours after the last dose. Deltamethrin was poorly absorbed and eliminated slowly. The absorbed deltamethrin was metabolized extensively and excreted in bile and urine with very little accumulation in major edible tissues. After the last dose, approximately 36-43% of the administered dose was eliminated in feces, with deltamethrin being the major portion (73-80%) of the total radioactive residues (TRR). 4-6% of the administered dose was eliminated in urine and 0.42-1.62% were secreted in milk.

TRRs in the various tissues were generally low (< 0.1 ppm) with the exception of liver (TRRs of up to 3.19 ppm), kidney (up to 2.24 ppm), udder (up to 0.62 ppm), abdominal fat (up to 0.56 ppm) and subcutaneous fat (up to 0.54 ppm). Deltamethrin was a predominant residue in liver (23-24% of the TRRs), kidney (32-35% of the TRRs) and fat (60-90% of the TRRs). In the gem-dimethyl labeled study, the metabolite $Br_2CA$ [3-(2,2-dibromoethenyl)-2,2-dimethyl-cyclopentane-carboxylic acid] was predominant in liver (23% of the TRRs), kidney (33% of the TRRs) and fat (16% of the TRRs). In the benzyl labeled study, PBAcid [3-phenoxy-benzoic acid] was a predominant metabolite in liver (32% of the TRRs) and kidney (23% of the TRRs).

In the **second study** two lactating dairy cows were dosed orally with capsules containing $^{14}$C-benzyl tralomethrin or $^{14}$C-dimethyl tralomethrin for three consecutive days at dose levels equivalent to 1.58 and 1.64 mg/kg bw/day, respectively.

The total amounts of radioactivity recovered from benzyl label and dimethyl label were below 51.77% of the administered dose (AD). The majority of the radioactivity was eliminated via the feces (up to 18.47% of the AD) and the urine (up to 34.58% of the AD). Total radioactivity in the entire milk production was below 0.39% of the AD. The liver (up to 0.83% of the AD), kidneys (0.07% of the AD), fat (0.06% of the AD) and muscle (less than 0.01% of the) accounted for the rest of the recovered residues.

The daily concentrations of radioactivity in the milk ranged from 0.028 to 0.110 ppm of the administered dose. The $^{14}$C concentrations peaked on after administration of the second dose capsule on day 2.

In blood, the radioactivity concentration increased over time, with the greatest concentrations appearing at the time of sacrifice. Among the tissues, the highest TRRs were found in liver (0.736 ppm), kidney (0.482 ppm) and fat (0.165 ppm). The muscle had the lowest TRRs at 0.019 ppm, followed by the blood.

Based on the benzyl label, the major residue in the milk, muscle and fat was deltamethrin, accounting for 77% of the TRRs (0.061 ppm), 91% of the TRRs (0.012 ppm) and 94% of the TRRs (0.054 ppm), respectively. The major metabolite in the liver was 3-phenoxy benzoyl-glutamic acid (mPBA-Glutamate) representing 44% of the TRRs and 3-phenoxybenzoic acid (mPBAcid) representing 13% of the TRRs. The kidney contained mPBAcid (16% of the TRRs) and deltamethrin (1% of the TRRs).

With the dimethyl label, the major residue in the milk and fat was deltamethrin accounting for 75% of the TRRs (0.063 ppm) and 76% of the TRRs (0.095 ppm), respectively. Muscle contained two major residues, deltamethrin and $Br_2CA$ accounting for 48% of the TRRs and 32% of the TRRs, respectively. The liver contained three metabolites, $Br_2CA$ (6% of the TRRs), $Br_2CA$-glycine (2% of the TRRs) and one metabolite, tentatively identified as c-OH-$Br_2CA$-lactone (12% of the TRRs). In the kidney, deltamethrin accounted for 2% of the TRRs. A major metabolite that accounted for 63% of the TRRs was tentatively identified as COOH-$Br_2CA$. A third metabolite (15% of the TRRs) was tentatively identified as an amino acid conjugate of $Br_2CA$.

A **third study** was conducted as an extension of the second, for the analysis of the unidentified metabolites in liver and kidney from a cow which was treated with [$^{14}$C]-gem-dimethyl tralomethrin. The unknown compounds were subjected to a wide range of chromatographic, chemical and mass spectroscopic techniques to further elucidate their identity. Although the various analytical procedures to which they were subjected to did not identify their nature, it did characterize them as polar molecules behaving as interconvertible acids and lactones.

In the **supplemental study**, deltamethrin was applied dermally once daily to lactating cows at a rate of 1.47 mg/kg/day or 1.50 mg/kg/day for three consecutive days. The TRR recoveries ranged from 90% to 123% of the applied dose for all matrices. The residues remained mainly around the application site: 19%-37% of the TRR in the enclosure and 36%-48% of the TRR in the skin wash/wipe. Low TRR were recovered in urine and feces (0.20%-0.59% of the applied dose) as well in the tissues (0.001-0.013 ppm; < 0.01% of the applied dose). The majority of the radioactive residues from milk was found in the cream (0.009-0.010 ppm; < 0.01% of the applied dose) and was not detectable in the skimmed milk.

Deltamethrin was the only detectable metabolite present in skin (96%-97% of the detected TRR; 169-266 ppm), renal fat (48%-59% of the detected TRR, 0.004-0.007 ppm) and cream (42%-55% of the detected TRR; 0.004-0.005 ppm). In liver and kidney samples, mPB-glutamate was the only metabolite identified from the samples treated with benzyl labelled deltamethrin (31%-33% of the detected TRR; 0.003-0.004 ppm). In the samples treated with gem-dimethyl labelled deltamethrin, several unknown metabolites were detected (0.4%-30.4% of the TRR; 0.001-0.003 ppm) each at very low levels.

### Poultry

Two poultry metabolism studies performed by oral administration of deltamethrin or tralomethrin were reviewed.

In the first study, the transformation of $^{14}C$ labeled (gem-dimethyl or benzyl) deltamethrin was determined in White Leghorn hens after oral administration of ~50 mg/kg bw on each of three consecutive days. Excreta and eggs were monitored during the study and for five days after the last dose. At 6, 18, 48 and 120 hours after the final dose the hens were sacrificed. Representative samples of liver, kidney, heart, subcutaneous and abdominal fat, breast and leg muscle and gizzard were collected.

About 83% of the administered dose was eliminated 24 hours after the last dose. Residues reached a peak on the fourth day (18 hours after the last dose). Tissue residues were generally very low in skeletal muscles (traces to 0.21 ppm), compared to those of liver and kidney. Residues in liver (up to 3.95 ppm) and kidney (trace to 2.52 ppm) were high yet diminished quickly after the dosing period. TRRs in tissues were consistently 2-3 times higher from the gem-dimethyl portion of the molecule than those from the benzyl moiety. This may, in part, be due to the lipophilic nature of the gem-dimethyl moiety of deltamethrin. Egg yolks contained considerably higher levels of residues than egg albumen. The data suggested that once deltamethrin and the metabolites were incorporated in the yolks, there was very little exchange from the yolk to the other body compartment. Consequently, radiocarbon was detected in egg yolks for several days after the last dose.

The nature of metabolites in various tissues could not be fully authenticated since the amounts of these residues were too small. Almost all the radioactivity extracted from the albumen and egg yolks was identified as deltamethrin. In liver, more than 90% of the TRR was estimated to be deltamethrin. In kidney, more than 80% of the TRRs were extracted and results showed four distinct regions corresponding to deltamethrin (31-35% of the TRRs), c-$Br_2$CA and c- and t-COOH-c-$Br_2$CA (27-28% of the TRRs), c-$CH_2$OH-c-$Br_2$CA and t-COOH-c-$CH_2$OH-c-$Br_2$CA-lactone (19-27% of the TRRS) and an unidentified component (up to 23% of the TRRs). In summary, the compounds identified indicated that the metabolic routes of deltamethrin in laying hens include hydrolysis of ester linkage, followed by hydroxylation of one or both gem-dimethyl groups, and hydroxylation of the 2'-, 4'-, 5- or 6-position of the phenoxybenzyl moiety.

In the second study two groups of five laying hens were administered radiolabelled tralomethrin for five consecutive days at a dose level of 10 mg/kg of diet/day. Body weights, food consumption, egg production, and general health and appearance were monitored and recorded throughout the study. Excreta were collected once daily and weighed as well. Animals were sacrificed approximately six hours after the administration of the final dose. Blood, heart, liver, kidneys, thigh muscle, breast muscle, fat, skin with fat, *gizzard* and the gastrointestinal (GI) tract with contents were collected. All samples were pooled by group and analyzed for radioactivity.

For the laying hens dosed with the [$^{14}$C-benzyl] tralomethrin, the total radioactivity recovered ranged from 94% to 107% of the total dose administered. The majority of the radioactivity was recovered in the excreta, with values ranging from 90% to 103% of the total dose. The rest of the recovered radioactivity was accounted for by the GI tract (3.85% to 4.32% of the total dose), liver (0.07% of the total dose), kidneys (0.05% of the total dose) and eggs (0.01% to 0.03% of the total dose). The extremely rapid clearance of tralomethrin from hens is demonstrated by these data. It was found that the fat, muscle and egg yolk contained exclusively deltamethrin (74%, 81% and 83% of the TRRs in the respective matrices; ppm values not provided). The liver contained deltamethrin (14%), 4'OH-deltamethrin (3%), 4'OH-mPBacid (9%), mPBacid (5%) and amino acid-conjugates (29%). The kidney contained deltamethrin (1%), 4'OH-mPBacid (7%) and amino acid-conjugates (43%). The rest of the TRRs in liver and kidney that were solubilized did not co-chromatograph with available standards. The chromatographic behavior of these metabolites indicated that they were much more polar than deltamethrin and more polar than mPBacid, as well.

Results were similar for the laying hens dosed with [$^{14}$C-dimethyl] tralomethrin. Total radioactivity recovered ranged from 88% to 92% of the total dose administered. The majority of the radioactivity was again found in the excreta, with values ranging from 86% to 90% of the total dose. The rest of the recovered radioactivity was accounted for by the GI tract (1% to 2% of the total dose), liver (0.14% to 0.16% of the total dose), kidneys (0.04% to 0.05% of the total dose) and eggs (0.01% to 0.03% of the total dose). The only residue found in substantial quantity in both the fat and egg yolk was deltamethrin (85% in the fat and 84% in the egg yolk). The muscle contained deltamethrin (32% of the TRRs) and $Br_2$CAcid (32%). The liver contained $Br_2$CAcid (52% of the TRRs) and amino acid-conjugates (15%). The kidney contained both $Br_2$CAcid (40%) and $Br_2$CAcid -glycine (21%). The rest of the TRRs in the kidney that were solubilized did not co-chromatograph with available standards. The chromatographic behaviour of these metabolites indicated that they were often more polar than $Br_2$CAcid.

These results indicate that the rapid debromination of tralomethrin is the first step in the metabolic pathway of tralomethrin. Deltamethrin is further metabolized by cleavage of the ester bond and hydroxylation of the 4' or 2' position. Products resulting from cleavage of the ester bond are sometimes found in their conjugated forms. The nature of the residue for tralomethrin and deltamethrin in poultry is thus understood.

### 1.1.4 Residue

**Definition**

The qualitative nature of deltamethrin residues in plant and animal is understood based on reviews of acceptable plant and animal metabolism studies.

The residue definition is cyclopropanecarboxylic acid, 3-(2,2-dibromoethenyl)-2,2-dimethyl-, (*S*)-cyano(3-phenoxyphenyl)methyl ester, (1*R*,3*R*)-, including the isomers cyclopropanecarboxylic acid, 3-(2,2-dibromoethenyl)-2,2-dimethyl-, (*S*)-cyano(3-phenoxyphenyl)methyl ester, (1*R*,3*S*)- and cyclopropanecarboxylic acid, 3-(2,2-dibromoethenyl)-2,2-dimethyl-, (*R*)-cyano(3-phenoxyphenyl)methyl ester, (1*R*,3*R*) for all commodities except milk and cyclopropanecarboxylic acid, 3-(2,2-dibromoethenyl)-2,2-dimethyl-, (*S*)-cyano(3-phenoxyphenyl)methyl ester, (1R,3*R*)-, including the isomers cyclopropanecarboxylic acid, 3-(2,2-dibromoethenyl)-2,2-dimethyl-, (*S*)-cyano(3-phenoxyphenyl)methyl ester, (1*R*,3*S*)- and cyclopropanecarboxylic acid, 3-(2,2-dibromoethenyl)-2,2-dimethyl-, (*R*)-cyano(3-phenoxyphenyl)methyl ester, (1*R*,3*R*) (calculated on the fat content) for milk.

There are no proposed changes to the present residue definition.

## 1.2 Analytical Methods

Exposure to pyrethrins and pyrethroids is most commonly evaluated by the analysis of urine and blood using gas chromatography (GC) combined with electron capture detection (ECD), flame ionization detection (FID), or mass spectrometry (MS) and high performance liquid chromatography (HPLC) coupled with ultraviolet (UV) detector. Recovery is generally high, and sensitivity is in the parts per billion (ppb) range.

### 1.2.1 Methods for Residue Analysis in Plants

**Method XM-09**, a GC-ECD data-gathering analytical method with an LOQ of 0.02 ppm, was found satisfactory for the analysis of αR-deltamethrin, cis-deltamethrin and trans-deltamethrin in cucurbit vegetables and pome fruits.

**Method ENC-6/92**, a GC-ECD method, was reviewed and validated as both data-gathering and enforcement methods in grain crops and processed fractions for the determination of deltamethrins three isomers. The LOQ was 0.05 ppm for each analyte in grain dust and 0.02 ppm for each analyte in all the other grain matrices.

**Method ENC-8/92** was validated as an updated Method ENC-6/92 for processed grain fractions, grain dust, whole grain from corn, wheat, sorghum and rice.

**Method HRAV-20**, a GC-ECD method with an LOQ of 0.05 ppm, was validated as a data-gathering and an enforcement method in plant commodities with high water, oil, protein, starch and acid content matrices, for the determination of residues of the three isomers cis-deltamethrin, trans-deltamethrin and αR-deltamethrin and residues of tralomethrin as cis-deltamethrin equivalents.

The HPLC-MS/MS analytical **Method 00855/M002** was found to be acceptable as a data-gathering analytical method for determination of residues of cis-deltamethrin in various plant matrices: barley, wheat, broccoli, corn, lettuce, melon, olive, pepper, sugar beet, tobacco, tomato and zucchini with LOQs of 0.01 and 0.05 ppm.

The GC-MS/MS or GC-MSD analytical **Method 00855/M003** was validated for determination of residues of deltamethrin in plant matrices with high oil and water content with LOQs of 0.01 and 0.05 ppm.

The GC-ECD analytical **Method DGM F01/97-0** was developed and validated for the determination of deltamethrin in plant matrices with high water, oil, protein and starch content with a reported LOQ of 0.02 ppm.

The Method **DGM F01/97-1** was developed by modification of Method DGM F01/97-0 and was successfully validated in plant matrices high water, oil, protein, starch and acid content, as well as in livestock commodities.

The **Method HRAV 7/78** a GLC-ECD method was reviewed and validated for the determination of tralomethrin, cis-, trans- and αR-deltamethrin in cottonseed and cottonseed fractions with an LOQ of 0.02ppm.

### 5.2.2 Methods for Residue Analysis of Food of Animal Origin

**Method HRAV-22 (ENC-2/93)** was reviewed and validated as both data-gathering and enforcement method in animal matrices for the determination of residues of deltamethrin as the three isomers: *cis*-deltamethrin, *trans*-deltamethrin and *αR*-deltamethrin and residues of tralomethrin as *cis*-deltamethrin equivalents. The limits of quantitation (LOQ) are reported as 0.007 ppm (combined, sum of the three analytes) in chicken, beef fat and 0.017 ppm (combined) in all other matrices.

A similar GLC-ECD **Method RE 48.01.26/5** was submitted for the analysis of deltamethrin in various sheep tissues. The stated sensitivity of the method is 1ppb with a recovery of 90%.

The GC-ECD **Method DGM F01/97-1** was submitted and validated for foodstuff of animal origin (milk, eggs, meat, fat, liver, kidney). Having an LOQ of 0.02 ppm, the specificity of the method was demonstrated by a confirmatory technique using a GC column with a different stationary phase.

### 5.2.3 Enforcement Analytical Methodology

Several methods submitted were reviewed and validated as enforcement analytical methods for the determination of residues of deltamethrin in various matrices: ENC-6/92, HRAV-20, HRAV 7/78, CFIA PMR-001-V1.6 for plant commodities and HRAV-22 for animal commodities.

### 5.2.4 Inter-Laboratory Validation (ILV)

All methods reviewed were validated by an independent laboratory with the exception of Method XM-09.

### 1.2.5 Multi-Residue Analytical Method (MRM)

The **Method DG/M 034-97-0**, previously reviewed and validated, was initially submitted as an adapted Dutch MRM 1 NO for the determination of the residues of deltamethrin and tralomethrin in potatoes, peaches, onions, and rape seed.

Deltamethrin was recovered with good results using the following USFDA MRM methods:

- Method 302 (E1-E5 = DG1-DG19)
- Method 302 (E1-E3 = C5 = DG1-DG19)
- Method 302 (E2/E3 = C1 = DG1-DG19)
- Method 302 (E7 = C6 = DG1-DG5, DG6-DG7, DG10, DG15-DG18, or DG16)
- Method 303 (E1-E5 = C1 or C2 = DG1-DG19)

The MRM **Method MCR/MD/1/DEL-4** is used as described in the Manual of Pesticide Residue Analysis, DFG, 1992, volume II, S23 p 333 – 342. The extract is analysed using gas-liquid chromatography equipped with an EC detector with an LOQ of 0.01 ppm.

## 1.3 Food Residues

### 1.3.1 Storage Stability

#### 1.3.1.1 Frozen Storage Stability in Plant Commodities

The frozen storage stability was reviewed in apples, cucumbers, lettuce, cottonseed, corn, cabbage wheat, tomato and soybeans.

*Crops*
Frozen storage stability data demonstrated that residues of deltamethrin were stable in five diverse crops: an oily commodity (cotton) for 19 months, a leafy vegetable (lettuce) for 16.5 months, a Brassica (cabbage) for 24 months, a fruit (apple) for 12 months, a fruiting vegetable (tomato) for 24 months, a cereal grain (wheat) for 12 months. Although, frozen storage stability was not demonstrated in a root crop, deltamethrin residues can be considered to be stable in all crops for at least 12 months.

*Processed Commodities*
Frozen storage stability data demonstrated that residues of deltamethrin were stable in cottonseed oil for 19 months, corn oil, meal and flour for 9 months, wheat flour and germ for 18 months, wheat bran for 20 months, and tomato wet pomace and puree for 17 months.

#### 1.3.1.2 Frozen Storage Stability in Animal Commodities

The frozen storage stability was reviewed for deltamethrin and tralomethrin in various poultry and ruminant commodities. As tralomethrin is determined analytically as deltamethrin equivalents, its frozen storage stability was determined in terms of deltamethrin equivalents and not as tralomethrin.

The data indicate that the residues of tralomethrin and deltamethrin are stable for up to 7 months in frozen milk, fat, muscle, liver and kidney of dairy cow under freezer conditions.

#### 1.3.1.3 Storage Stability of Working Solutions in Analytical Methodology

There are no storage stability studies for working solutions submitted by the registrant. The registrant is required to submit such storage stability studies for any expansion of use of deltamethrin.

In a corn storage stability study, the recoveries for the acetone storage stability on Day 0 ranged from 105% to 125% with a mean and standard deviation of 114% ±9.3 (n=4) for cis deltamethrin. Day 3 recoveries ranged from 81% to 118% with a mean and standard deviation of 101% ± 15 (n=4) for cis-deltamethrin and Day 7 recoveries ranged from 78% to 106% with a mean and standard deviation of 96% ± 13 (n=4) for cis deltamethrin.

No significant conversion of cis deltamethrin to trans-deltamethrin or alpha-R deltamethrin was observed.

### 1.3.2 Crop Residues

Crop residue data were available from registrant submitted field trial studies, the CFIA pesticide monitoring program and the USDA PDP pesticide monitoring program.

**Field trial residue data**

A large database of field trial studies were submitted and reviewed. The submitted studies cover a large range of application rates, preharvest intervals, crops and growing zones that are more or less adequate to the registered Canadian usage of deltamethrin, therefore only the appropriate residue data was selected to be used in the determination of the magnitude of residues in the various commodities.

A summary of the residue data in the registered commodities (Canada and US) determined as highest average field trial (HAFT) and supervised trial median residue (STMR) for the trials performed at or near Canadian label rate is presented below. Field trial data from climatic zones outside of Canada and at rates higher than the Canadian label rate are included only where they represent the best available data.

**Table 1 Deltamethrin residues in plant commodities**

| Commodity | Residues[1] (mg/kg) | | | |
|---|---|---|---|---|
| | mean | median | max | HAFT |
| Almonds | 0.06 | 0.06 | 0.06 | 0.06 |
| Apple juice | 0.15 | 0.15 | 0.15 | 0.15 |
| Apple | 0.067 | 0.063 | 0.137 | 0.08 |
| Asparagus | 0.012 | 0.01 | 0.031 | 0.031 |
| Barley | 0.003 | 0.003 | 0.003 | 0.003 |

| Commodity | Residues` (mg/kg) | | | |
|---|---|---|---|---|
| | mean | median | max | HAFT |
| Blueberry | 0.05 | 0.032 | 0.156 | 0.156 |
| Broccoli | 0.023 | 0.001 | 0.08 | 0.08 |
| Brussels sprouts | 0.037 | 0.02 | 0.069 | 0.069 |
| Cabbage | 0.02 | 0.02 | 0.02 | 0.02 |
| Canola | 0.048 | 0.046 | 0.117 | 0.091 |
| Canola oil | 0.06 | 0.06 | 0.06 | 0.06 |
| Cauliflower | 0.005 | 0.004 | 0.01 | 0.01 |
| Corn | 0.06 | 0.06 | 0.06 | 0.06 |
| Corn oil | 0.06 | 0.06 | 0.06 | 0.06 |
| Corn flour | 0.05 | 0.05 | 0.05 | 0.05 |
| Corn starch | 0.06 | 0.06 | 0.06 | 0.06 |
| Corn sweet | 0.003 | 0.003 | 0.006 | 0.006 |
| Flax | 0.001 | 0.001 | 0.001 | 0.001 |
| Head and stem brassica (5A) | 0.016 | 0.016 | 0.08 | 0.08 |
| Kale | 0.004 | 0.004 | 0.004 | 0.004 |
| Lentils | 0.003 | 0.003 | 0.003 | 0.003 |
| Mustard / Oilseed mustard | 0.002 | 0.002 | 0.002 | 0.002 |
| Oats | 0.001 | 0.001 | 0.001 | 0.001 |
| Olive oil | 1.948 | 2.4 | 2.6 | 1.942 |
| Olives | 0.289 | 0.168 | 1.9 | 1.7 |
| Onions | 0.01 | 0.01 | 0.01 | 0.01 |
| Peaches | 0.011 | 0.009 | 0.022 | 0.022 |
| Pears | 0.003 | 0.001 | 0.016 | 0.016 |
| Peppers | 0.057 | 0.04 | 0.224 | 0.155 |
| Potato | 0.003 | 0.001 | 0.01 | 0.01 |
| Radish | 0.18 | 0.189 | 0.231 | 0.209 |
| Radish tops | 1.645 | 1.456 | 3.443 | 3.262 |
| Saskatoon berry | 0.033 | 0.03 | 0.05 | 0.05 |
| Soybeans | 0.048 | 0.05 | 0.05 | 0.05 |
| Soybean oil | 0.05 | 0.05 | 0.05 | 0.05 |
| Strawberries | 0.005 | 0.005 | 0.008 | 0.008 |
| Sugar beets | 0.001 | 0.001 | 0.001 | 0.001 |
| Summer squash | 0.067 | 0.062 | 0.079 | 0.078 |
| Sunflowers | 0.005 | 0.001 | 0.013 | 0.013 |
| Tobacco | 0.06 | 0.039 | 0.158 | 0.158 |
| Tomato | 0.012 | 0.012 | 0.02 | 0.02 |
| Wheat | 0.016 | 0.015 | 0.03 | 0.03 |
| Wheat flour | 0.008 | 0.008 | 0.008 | 0.008 |
| Wheat bran | 0.099 | 0.099 | 0.099 | 0.099 |
| Wheat oil | 0.407 | 0.407 | 0.44 | 0.44 |

## CFIA residue monitoring data

A summary of CFIA monitoring residue values determined in the last 5 years and employed in the dietary risk assessment is presented in Appendix VIII, Table 1.

### 1.3.3 Livestock Residues

Five acceptable livestock feeding studies with deltamethrin or a mixture deltamethrin / tralomethrin were reviewed. They were performed on lactating dairy cows and on poultry at feeding rates that encompassed the balanced dietary burden estimates and exaggerated rates. In animals, tralomethrin is converted directly to deltamethrin by debromination as the first step in metabolism. This conversion is so rapid that tralomethrin is not detected in any tissues. Therefore, the dosing of tralomethrin can be considered as totally comprised of deltamethrin once inside the animal's system.

The residues determined were taken into consideration when calculating the anticipated residues in animal commodities based on the more balance diet calculator (Table 2).

## Livestock Dietary Burden

Based on residues of plant commodities, livestock dietary burdens were estimated based on the registered uses of deltamethrin. Based on the blending capacity of the commodities, STMR or HAFT residues were used in the more balanced diet (MBD) calculator. These calculations are presented below.

**Table 2 Determination of the More Balanced Diet (MBD)**

| Crop | Commodity | Type | Residue | | % DM | % Diet | Dietary Contribution |
|---|---|---|---|---|---|---|---|
| | | | ppm | Input | | | ppm |
| **Beef Cattle** | | | | | | | |
| Corn, field | Stover | R | 10.52 | HR | 83 | 15 | 1.901 |
| Wheat | Milled byproducts | CC | 0.099 | STMR | 88 | 40 | 0.045 |
| Corn, field | Milled byproducts | CC | 0.06 | STMR | 85 | 40 | 0.028 |
| Canola | Meal | PC | 0.062 | STMR | 88 | 5 | 0.004 |
| **Total** | | | | | | **100** | **1.98** |
| **Dairy Cattle** | | | | | | | |
| Wheat | forage | R | 4.106 | HR | 25 | 20 | 3.285 |
| Corn, field | Stover | R | 10.52 | HR | 83 | 15 | 1.901 |
| Corn, sweet | Stover | R | 10.52 | HR | 83 | 10 | 1.267 |
| Apples | Pomace, wet | CC | 3.3 | STMR | 40 | 10 | 0.825 |
| Wheat | Milled byproducts | CC | 0.099 | STMR | 88 | 30 | 0.034 |
| Corn, field | Milled byproducts | CC | 0.06 | STMR | 85 | 5 | 0.004 |
| Canola | Meal | PC | 0.062 | STMR | 88 | 10 | 0.007 |
| **Total** | | | | | | **100** | **7.32** |
| **Poultry** | | | | | | | |
| Wheat | Milled byproducts | CC | 0.099 | STMR | NA | 50 | 0.050 |
| Corn, field | Grain | CC | 0.06 | STMR | NA | 25 | 0.015 |
| Canola | Meal | PC | 0.062 | STMR | NA | 15 | 0.009 |
| Cotton | Meal | PC | 0.06 | STMR | NA | 10 | 0.006 |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Total** | | | | | | **100** | **0.08** |
| **Swine** | | | | | | | |
| Wheat | Milled byproducts | CC | 0.099 | STMR | NA | 50 | 0.050 |
| Corn, field | Grain | CC | 0.06 | STMR | NA | 35 | 0.021 |
| Canola | Meal | PC | 0.062 | STMR | NA | 15 | 0.009 |
| **Total** | | | | | | **100** | **0.08** |

**NA = Not Applicable, HR = Highest Residue, STMR = Supervised Trial Median Residue**

Based on the dietary burden estimates, anticipated residue values for animal commodities were determined and are presented below.

### Table 3 Anticipated Residue Values in Animal Commodities Used for Refinement of Dietary Exposure Assessment

| **Animal Commodity** | **MRLs (ppm)** | **Dietary Burden** | **Feeding Level, Linear regression or Residue to feed ratio** | **Residues observed in feeding study (ppm)** | **Anticipated Residues (ppm)** | **Calculation** |
|---|---|---|---|---|---|---|
| | | **MRBD[1]** | | | | |
| Combined Deltamethrin Residues | | | | | | |
| Whole Milk | 0.05 (based on milk fat) | 7.32 ppm MRBD for dairy cattle | Linear regression | y = 0.0013x | 0.0095 | 0.0013 × MRBD |
| Milk Fat | | 7.32 ppm MRBD for dairy cattle | Linear regression | y = 0.0035x | 0.0256 | 0.0035 × MRBD |
| Cattle Muscle | 0.02 | 1.98 ppm MRBD for beef cattle | 2, 6, 20 ppm feeding levels | All < 0.01 | 0.0010 | [Residues / Feeding level (20 ppm)] × MRDB |
| Cattle Liver | 0.02 | | | | | |
| Cattle Kidney | 0.02 | | | | | |
| Cattle Fat | 0.05 | | Linear regression | y = 0.0012x | 0.00024 | 0.0012 × MRBD |
| Eggs | 0.02 | 0.08 ppm MRBD for poultry | Linear regression | y = 0.0018x | 0.0001 | 0.0018 × MRBD |
| Poultry Muscle | 0.02 | | 2, 6, 20 ppm feeding levels | All < 0.02 | 0.00008 | [Residues / Feeding level (20 ppm)] × MRDB |
| Poultry Liver | 0.02 | | | | | |
| Poultry Fat | 0.05 | | Linear regression | y = 0.0213x | 0.0017 | 0.0213 × MRBD |
| Swine Muscle | 0.02 | 0.08 ppm MRBD for swine | 2, 6, 20 ppm feeding levels (cattle) | All < 0.01 | 0.00004 | [Residues / Feeding level (20 ppm)] × MRDB |
| Swine Liver | 0.02 | | | | | |
| Swine Kidney | 0.02 | | | | | |
| Swine Fat | 0.05 | | Linear regression | y = 0.0012x | 0.0001 | 0.0012 × MRBD |

[1] MRBD = maximum reasonable balanced diet

A summary of feed residues used in the determination of the calculation of the Maximum Theoretical Dietary Burden MTDB and the anticipated animal residues is presented in Appendix VIII, Table1.

### 1.3.4 Confined and Field Crop Rotation

A confined rotational crop study was reviewed in which various trials were performed on barley, lettuce and carrots. The crops were planted at intervals of 30, 120 and 365 days following the final application of $^{14}$C-deltamethrin. Plants were harvested at approximately half maturity and at full maturity according to standard agricultural practices. The confined rotational crop results support a 30-day plant-back interval for all crops from a food residue point of view.

No rotational crop studies are required for the established crops registered in Canada.

### 1.3.5 Processed Food/Feed Data

The usage or transformation process, employed for the various crops for transforming them in valuable commodities, has an important impact on the residue level of a particular pesticide or metabolite in the respective commodities. Studies for the fate of the residues following consumer practices or industrial processing were submitted and reviewed by PMRA. A summary of the processing factors derived from field trial data is provided below.

**Table 4 Processing Factors (PFs) or Concentration/Reduction Factors Used in Dietary Analyses**

| Processed Commodity | PFs | Source |
|---|---|---|
| Apple dried | 8.0 | Default |
| Apple juice | 0.24 | Experimental |
| Barley flour | 0.5 (wheat)[1] | Experimental |
| Barley bran | 3.3 (wheat) | |
| Beef dried | 1.92 | Default |
| Canola oil (rapeseed oil) | 0.9 | Experimental |
| Corn flour | 1.8 | Experimental |
| Corn meal | 1.3 | |
| Corn starch | 0.4 | |
| Corn oil | 6.3 | |
| Corn syrup | 1.5 | Default |
| Grape juice | 1.2 | Default |
| Grapefruit juice | 2.1 | Default |
| Oat bran | 3.3 (wheat) | Experimental |
| Oat flour | 0.5 (wheat) | |
| Onion dried | 9.0 | Default |
| Orange juice | 1.8 | Default |
| Peach dried | 7.0 | Default |
| Pear dried | 6.25 | Default |

| Processed Commodity | PFs | Source |
|---|---|---|
| Potato chips | 1 | Experimental |
| Potato dried | 1 | Experimental |
| Soybean meal | 0.94 | Experimental |
| Soybean oil | 0.94 | |
| Tomato paste | 0.34 | Experimental |
| Tomato puree | 0.34 | Experimental |
| Tomato dried | 14.3 | Default |
| Tomato juice | 1.5 | Default |
| Wheat flour | 0.5 | Experimental |
| Wheat bran | 3.3 | |

[1] PF translation.

### 1.3.6 Residues in food handling establishments (FHE)

As deltamethrin is registered in US for use in food handling establishments FHE, a general tolerance of 0.05 ppm was established in US on food following the treatment of the FHE with deltamethrin.

A supplementary food residue study for a crack and crevice treatment of FHE with deltamethrin was provided by the registrant and reviewed by PMRA. The study demonstrated that following the application of DeltaDust® as a crack and crevice treatment in a confined space at 1X and 4X rates with covered and uncovered food commodities for two hours, quantifiable residues will not be found on those foods exposed to the highest rate, uncovered, and out of their original packaging (Table 5).

**Table 5 Deltamethrin Residues in Uncovered Food Items Following a Crack and Crevice Application in FHE**

| Food item | Residue (ppm) | |
|---|---|---|
| | In the package | Out of package |
| milk | < 0.010 | < 0.010 |
| butter | < 0.010 | < 0.010 |
| cooked meat | < 0.010 | < 0.010 |
| uncooked meat | < 0.010 | < 0.010 |
| flour | < 0.010 | < 0.010 |
| rice | < 0.010 | < 0.010 |
| bread | < 0.010 | < 0.010 |
| lettuce | none[a] | < 0.010 |

| | | |
|---|---|---|
| cooked apples | none[a] | < 0.010 |
| raw apples | none[a] | < 0.010 |
| candy | < 0.010 | < 0.010 |
| sugar | < 0.010 | < 0.010 |

[a] none: these foods were not commercially packaged

### 1.3.7 Data Gaps

Sufficient information was available to adequately assess the dietary exposure and risk from exposure to deltamethrin. No deficiencies were identified in the residue chemistry database from previous PMRA Reviews. No further data are required for continued registration.

# Appendix VIII CFIA Monitoring Data Used in Dietary Analysis

Residues of deltamethrin were not detected for any sample analyzed in the CFIA food residue monitoring programs, with the exception of one fresh bean sample. In total, of 19000 of domestic and imported food samples were analyzed during the period of 2001-2010. Residue estimates were conservatively based on ½ of the average analytical level of quantitation (LOQ) for the CFIA monitoring program, with the exception of fresh beans, for which the residue estimate is based on the highest detected residue. The residues values were further processed using a weighted residue average based on % of treated crops, statistics on domestic production and imported quantities of crop commodities as well on the different LOQ reported for the analytical methodology used in the various years of monitoring. The formula used to calculate the reside estimates is presented below:

CT Weighted ½ LOQ
= (%CT Canada × % domestic production × ½ LOQ domestic) + (%CT in U.S. × % U.S. crops imported × ½ US LOQ) + Σ(%CT in other countries × % imports from other countries × ½ LOQ in other countries)

Canadian Weighted %CT
= (%CT Canada × % domestic production) + (%CT in U.S. × % U.S. crops imported) + (%CT in other countries × % imports from other countries)

A summary of the weighted ½ LOQ estimates is presented below.

**Table 1 CFIA Monitoring Residue Data**

| Commodity | Average residue - ½ LOQ (ppm) | | CT Weighted Average ½ LOQ (ppm) | Max LOQ (ppm) |
|---|---|---|---|---|
| | domestic | import | total | |
| Apple, Fresh | 0.00445 | 0.00493 | 0.004606 | 0.011 |
| Artichoke, Fresh | 0.00550 | 0.00425 | 0.004200 | 0.011 |
| Asparagus, Fresh | 0.00431 | 0.00453 | 0.004513 | 0.011 |
| Bean, Fresh | 0.00448 | 0.01670[1] | 0.000510 | 0.0167[1] |
| Beet, Fresh | 0.00433 | 0.00521 | 0.005156 | 0.011 |
| Blueberry, Fresh | 0.00443 | 0.00471 | 0.004486 | 0.011 |
| Broccoli, Fresh | 0.00466 | 0.00476 | 0.004668 | 0.011 |
| Brussels Sprout, Fresh | 0.00438 | 0.00474 | 0.004531 | 0.011 |
| Cabbage, Fresh | 0.00499 | 0.00451 | 0.004850 | 0.011 |
| Cantaloupe, Fresh | 0.00515 | 0.00512 | 0.005207 | 0.011 |
| Carrot, Fresh | 0.00483 | 0.00475 | 0.001311 | 0.011 |
| Cassava, Fresh | | 0.00521 | 0.005500 | 0.011 |
| Cauliflower, Fresh | 0.00454 | 0.00485 | 0.004736 | 0.011 |
| Celery, Fresh | | 0.00484 | 0.003583 | 0.011 |
| Corn, Fresh (sweet) | 0.00425 | 0.00492 | 0.004280 | 0.011 |
| Cucumber, Fresh | 0.00502 | 0.00469 | 0.000893 | 0.011 |

| **Commodity** | **Average residue - ½ LOQ (ppm)** | | **CT Weighted Average ½ LOQ (ppm)** | **Max LOQ (ppm)** |
|---|---|---|---|---|
| | domestic | import | total | |
| Egg | 0.00750 | 0.00750 | 0.007500 | 0.015 |
| Eggplant, Fresh | 0.00498 | 0.00485 | 0.003329 | 0.011 |
| Ginger, Fresh | | 0.00374 | 0.003700 | 0.011 |
| Grape, Fresh | 0.00496 | 0.00464 | 0.002096 | 0.011 |
| Grapefruit, Fresh | | 0.00475 | 0.001094 | 0.011 |
| Kale, Fresh | | 0.00550 | 0.004405 | 0.011 |
| Leaf Lettuce, Fresh | 0.00550 | 0.00550 | 0.000086 | 0.011 |
| Leek, Fresh | 0.00550 | 0.00432 | 0.002639 | 0.011 |
| Lemon, Fresh | | 0.00472 | 0.001894 | 0.011 |
| Lettuce, Fresh | 0.00460 | 0.00484 | 0.000096 | 0.011 |
| Lime, Fresh | | 0.00519 | 0.001894 | 0.011 |
| Mushroom, Fresh | 0.00459 | 0.00404 | 0.000128 | 0.011 |
| Nectarine, Fresh | 0.00474 | 0.00456 | 0.000855 | 0.011 |
| Onion Green, Fresh | 0.00479 | 0.00501 | 0.004706 | 0.011 |
| Onion, Fresh | 0.00447 | 0.00458 | 0.004632 | 0.011 |
| Orange, Fresh | | 0.00461 | 0.001193 | 0.011 |
| Pea, Fresh | 0.00472 | 0.00445 | 0.000322 | 0.011 |
| Peach, Fresh | 0.00452 | 0.00467 | 0.004636 | 0.011 |
| Pear, Fresh | 0.00540 | 0.00472 | 0.004966 | 0.011 |
| Pepper (greenhouse), Fresh | 0.00445 | 0.00550 | 0.004704 | 0.011 |
| Pepper, Fresh | 0.005167 | 0.00451 | 0.004704 | 0.011 |
| Plum, Fresh | 0.00441 | 0.00487 | 0.001378 | 0.011 |
| Potato, Fresh | 0.00450 | 0.00461 | 0.004504 | 0.011 |
| Radish, Fresh | 0.00455 | 0.00493 | 0.002975 | 0.011 |
| Spinach, Fresh | 0.00455 | 0.00450 | 0.000221 | 0.011 |
| Squash, Fresh | 0.00445 | 0.00440 | 0.001509 | 0.011 |
| Strawberry, Fresh | 0.00519 | 0.00484 | 0.004906 | 0.011 |
| Tomato (greenhouse), Fresh | 0.00530 | 0.00554 | 0.004819 | 0.011 |
| Tomato, Fresh | 0.00452 | 0.00468 | 0.004819 | 0.011 |
| Watermelon, Fresh | 0.00298 | 0.00455 | 0.004477 | 0.011 |

Note 1: Value represents detected residue

# Appendix IX Aggregate Risk Assessment

## Table 1 Oral Exposure Estimates for Aggregate Assessment for Children (1 to <2 years old)

| Scenario | Lifestage | Oral Exposure (mg/kg bw/day)[a] | Chronic Dietary Exposure (Food + Water) (mg/kg bw/day) | Total Exposure (mg/kg bw/day)[b] | Aggregate MOE[c] |
|---|---|---|---|---|---|
| **Lawns and Turf Scenario** | | | | | |
| Children on Turf (hand-to-mouth exposure) | Children (1 to < 2) | 0.000822 | 0.000917 | 0.0017 | 580 |

[a] Postapplication exposure estimates are from the incidental oral exposure (hand-to-mouth) (see Table 5.4)

[b] Total exposure (mg/kg bw/day) = Incidental Oral Exposure (mg/kg bw/day) + Chronic Dietary Exposure (mg/kg bw/day)

[c] Based on an oral LOAEL = 1 mg/kg bw/day with a target MOE of 300

# Appendix X Supplemental Maximum Residue Limit Information – International Situation and Trade Implications

MRLs may vary from one country to another for a number of reasons, including differences in pesticide use patterns and the locations of the field crop trials used to generate residue chemistry data. For animal commodities, differences in MRLs can be due to different livestock feed items and practices. A comparison between Canadian and Codex MRLs and US Tolerances is presented below.

**Table 1 Comparison between Canadian MRL, Codex MRL and US Tolerances**

| Commodity | MRL (ppm) | US Tolerances (ppm) | Codex MRL (ppm) |
|---|---|---|---|
| African eggplants | 0.3 | | |
| Almond, hulls | | 2.5 | |
| Apple | | | 0.2 |
| Apple, wet pomace | | 1 | |
| Artichoke, globe | | 0.5 | |
| Barley, bran | | 5 | |
| Bell peppers | 0.3 | | |
| Borage seeds | 0.2 | | |
| Broccoli | 3.5 | | 0.1 |
| Brussels sprouts | 3.5 | | 0.1 |
| Bush tomatoes | 0.3 | | |
| Cabbages | 3.5 | | 0.1 |
| Carrot | | | 0.02 |
| Cauliflowers | 3.5 | | 0.1 |
| Chinese broccoli | 3.5 | | 0.1 |
| Chinese mustard cabbages | 3.5 | | 0.1 |
| Citrus fruits | | | 0.02 |
| Coconas | 0.3 | | |
| Corn, field, forage | | 0.7 | |
| Corn, field, refined oil | | 2.5 | |
| Corn, field, stover | | 5 | |
| Corn, pop, stover | | 5 | |
| Corn, sweet, forage | | 10 | |
| Corn, sweet, kernel plus cob with husks removed | | 0.05 | 0.02 |

| Commodity | MRL (ppm) | US Tolerances (ppm) | Codex MRL (ppm) |
|---|---|---|---|
| Corn, sweet, stover | | 15 | |
| Cotton, refined oil | | 0.2 | |
| Cotton, undelinted seed | | 0.04 | |
| Cuphea seeds | 0.2 | | |
| Currant tomatoes | 0.3 | | |
| Dry soybeans | 0.1 | | |
| Echium seeds | 0.2 | | |
| Eggplants | 0.3 | | |
| Eggs | 0.02 | 0.02 | |
| Fat of cattle | 0.05 | 0.05 | 0.5 |
| Fat of goats | 0.05 | 0.05 | 0.5 |
| Fat of hogs | 0.05 | 0.05 | 0.5 |
| Fat of horses | 0.05 | 0.05 | 0.5 |
| Fat of poultry | 0.05 | 0.05 | 0.5 |
| Fat of sheep | 0.05 | 0.05 | 0.5 |
| Flaxseeds | 0.2 | | |
| Fruit, pome, Group 11 | | 0.2 | |
| Garden huckleberries | 0.3 | | |
| Goji berries | 0.3 | | |
| Gold of Pleasure seeds | 0.2 | | |
| Groundcherries | 0.3 | | |
| Grain, aspirated fractions | | 65 | |
| Grain, cereal, Group 15, except sweet corn | | 1 | 2 |
| Grapes | | | 0.2 |
| Hare's ear mustard seeds | 0.2 | | |
| Hazelnut | | | 0.02 |
| Leafy vegetables (except brassicas) | | | 2 |
| Leek | | | 0.2 |
| Legume vegetables | | | 0.2 |
| Lychee* | | 0.2 | |
| Kohlrabies | 3.5 | | 0.1 |
| Martynias | 0.3 | | |
| Meat byproducts of cattle | 0.02 | 0.05 | 0.03 |

| Commodity | MRL (ppm) | US Tolerances (ppm) | Codex MRL (ppm) |
|---|---|---|---|
| Meat byproducts of goats | 0.02 | 0.05 | 0.03 |
| Meat byproducts of hogs | 0.02 | | 0.03 |
| Meat byproducts of horses | 0.02 | 0.05 | |
| Meat byproducts of poultry | 0.02 | 0.02 | 0.02 |
| Meat byproducts of sheep | 0.02 | 0.05 | 0.03 |
| Meat of cattle | 0.02 | 0.02 | |
| Meat of goats | 0.02 | 0.02 | |
| Meat of hogs | 0.02 | | |
| Meat of horses | 0.02 | 0.02 | |
| Meat of poultry | 0.02 | 0.02 | 0.1 |
| Meat of sheep | 0.02 | 0.02 | |
| Milk | 0.05 | | 0.05 |
| Milk, fat (reflecting 0.02 ppm in whole milk) | | 0.1 | |
| Milkweed seeds | 0.2 | | |
| Mushroom | | | 0.05 |
| Mustard seeds (oilseed type) | 0.2 | | |
| Napa Chinese cabbages | 3.5 | | 0.1 |
| Naranjillas | 0.3 | | |
| Nectarines | | | 0.05 |
| Non-bell peppers | 0.3 | | |
| Nut, tree, Group 14 | | 0.1 | |
| Oil radish seeds | 0.2 | | |
| Okras | 0.3 | | |
| Olives | 1 | | 1 |
| Onion, bulb | | 0.1 | 0.05 |
| Onion, green | | 1.5 | |
| Peach | | | 0.05 |
| Pea eggplants | 0.3 | | |
| Pepinos | 0.3 | | |
| Plums (including prunes) | | | 0.05 |
| Poppy seeds | 0.2 | | |
| Potatoes | 0.04 | | 0.01 |
| Pulses | | | 1 |
| Radish | | | 0.01 |

| Commodity | MRL (ppm) | US Tolerances (ppm) | Codex MRL (ppm) |
|---|---|---|---|
| Radish, tops |  | 4 |  |
| Rapeseeds (canola) | 0.2 | 0.2 |  |
| Rice, hulls |  | 2.5 |  |
| Rye, bran |  | 5 |  |
| Roselles | 0.3 |  |  |
| Scarlet eggplants | 0.3 |  |  |
| Sesame seeds | 0.2 |  |  |
| Sorghum, grain, forage |  | 0.5 |  |
| Sorghum, grain, stover |  | 1 |  |
| Soybean, seed |  | 0.1 |  |
| Soybean, hulls |  | 0.2 |  |
| Starfruit* |  | 0.2 |  |
| Strawberries |  |  | 0.2 |
| Sunberries | 0.3 |  |  |
| Sunflower, seed |  | 0.1 | 0.05 |
| Sweet rocket seeds | 0.2 |  |  |
| Tea (green, black, fermented, dried) |  |  | 5 |
| Tomatillos | 0.3 |  |  |
| Tomatoes | 0.3 | 0.2 | 0.3 |
| Tomato, paste |  | 1 |  |
| Tomato, puree |  | 1 |  |
| Tree tomatoes | 0.3 | 0.2 |  |
| Vegetable, cucurbit, Group 9 |  | 0.3 | 0.2 |
| Vegetable, fruiting, Group 8 |  | 0.2 | 0.2 |
| Vegetable, root, except sugar beet, Subgroup IB |  | 0.2 |  |
| Vegetable, tuberous and corm, Subgroup IC |  | 0.04 |  |
| Walnuts |  |  | 0.02 |
| Wheat, bran |  | 5 | 5 |
| Wheat, flour |  |  | 0.3 |
| Wheat wholemeal |  |  | 2 |

# Appendix XI Environmental Exposure and Risk Assessment for Deltamethrin

## Table 1 Summary of Fate Processes for deltamethrin in the Terrestrial Environment

| Process | $T_{1/2}$ or $DT_{50}$ (days) | $DT_{90}$ | Kinetics | Comments | PMRA Reference (original study / foreign review) |
|---|---|---|---|---|---|
| **Abiotic transformation** | | | | | |
| Hydrolysis 25°C, 30 days | pH 5: Stable<br>pH 7: Stable<br>pH 9: 2.5 d | nr | SFO | May be an important route of transformation under alkaline conditions | 1549438 / 2212040 and 2212041 |
| Hydrolysis 23°C, 30 days | pH 8: 31 d | nr | SFO | | 1549437 / 2212041 |
| Phototransformation soil (sandy loam soil, pH 7.5, 0.6% OM, 25°C) | 9 d | nr | SFO | not a major route of transformation | 1549439 / 2212042 |
| **Aerobic Soil Biotransformation** | | | | | |
| Fine sandy loam: (pH 5.9, 1.0% OM, 25°C, 128 days) | | | | Non-persistent | 1549454 / 2212042 |
| 22.4 g a.i./ha | 13.9 d | 230 d | IORE | | |
| 224 g a.i./ha | 19.2 d | 222 d | IORE | | |
| Silt loam:<br>(pH 5.8, 0.7% OM, 25oC, 128 days) | | | | Slightly persistent | |
| 22.4 g a.i./ha | 20.8 d | 203 d | IORE | | |
| 224 g a.i./ha | 18.8 d | 176 d | IORE | | |
| Fine sandy loam:<br>(pH 5.9, 1.0% OM, 64 days) | | | | Slightly to moderately persistent | 1549446 / 2212040 and 2212042 |
| 10°C | 51.1 | 87 d | IORE | | |
| 25°C | 14.2 | 77 d | DFOP | | |
| 40°C | 30.3 | 101 d | SFO | | |
| Fine sandy loam: pH 5.9, 1.0% OM, 25°C, 64 days | | | | Non-persistent | 1549458 / 2212041 |
| 22.4 g a.i/ha treatment | 6.12 | 99.6 | IORE | | |
| 224 g a.i./ha treatment | 8.14 | 77.5 | IORE | | |
| Silty clay loam: pH 7.5, 2.3% OM, 25°C, 64 days | | | | Slightly persistent | |
| 22.4 g a.i/ha treatment | 17.5 | 222 | IORE | | |
| 224 g a.i./ha treatment | 17.1 | 150 | IORE | | |

| Process | $T_{1/2}$ or $DT_{50}$ (days) | $DT_{90}$ | Kinetics | Comments | PMRA Reference (original study / foreign review) |
|---|---|---|---|---|---|
| | | | | | |
| Sol de Versailles | 20 (at 20°C)<br>12 (at 35°C) | NR | SFO | Slightly persistent (at 20°C) | 1589448 |
| Sol de Versailles + terreaux | 50 (at 20°C)<br>40 (at 35°C) | NR | SFO | Moderately persistent | |
| Sandy clay loam: pH 7.9, 2.2% OM, 25°C, 16 weeks | 35.7 | 114 | SFO | Slightly persistent | 1589455 / 2212044 |
| Organic soil: pH 5.7, 40.6% OC, 21°C | 72 days | NR | SFO | Moderately persistent | PMRA 1589457 / 2212040 and 2212042 |
| Sandy loam soil: pH 8.1, 0.5% OM, 25°C, 181 days | 17.4 | 97.6 | IORE | Slightly persistent | 1589445 |
| Terre de Versaille soil<br>260 days; soil properties not reported | 25 (at 20°C)<br>18 (at 35°C) | NR | SFO | Slightly persistent | 1589449 |
| Sandy clay soil: 25°C | 28 | NR | NR | Slightly persistent | 2212044 |
| **Anaerobic Soil Biotransformation** | | | | | |
| Fine sandy loam soil: pH 5.9, 8.5% OM, 25°C, 64 days | 95.3 – 114 | 317 - 377 | SFO | Moderately persistent | 1589461 / 2212040 and 2212042 |
| Sandy loam soil: pH 8.1, 0.5% OM, 90 days | 20 | 135 | IORE | Slightly persistent | 1589460 |
| 25°C; study duration and soil characteristics not reported | 32, 36, 69, 100 and 105 | NR | NR | Slightly to moderately persistent | 2212041 |
| **Mobility** | | | | | |
| Adsorption:<br>deltamethrin | Arizona I – Sandy loam | Kd = 1590 | Koc = 2741742 | Immobile | 1589464 / 2212040 |
| | Arizona II – Sandy loam | Kd = 2067 | Koc = 890725 | | |
| | Arizona III – Clay | Kd = 2512 | Koc = 1082613 | | |
| | Silty Clay loam | Kd = 4282 | Koc = 527297 | | |
| | Arkansas silt loam | Kd = 2612 | Koc = 346174 | | 1589468 |
| | Georgia silt loam | Kd = 3537 | Koc = 435547 | | |
| | Texas sandy loam | Kd = 1251 | Koc = 209587 | | |
| Adsorption:<br>m – phenoxybenzoic acid (PBaC) | AZ3 – clay | Kd = 0.73 | Koc = 319 | Moderately to moderately mobile | 1589466 |
| | MS – Silty clay loam | Kd = 1.5 | Koc = 185 | | |
| | USA – Sandy loam | Kd = 2.55 | Koc = 107 | | |
| | MI – Clay loam | Kd = 2.65 | Koc = 51 | | |
| Adsorption:<br>3-(2,2-dibromovinyl)-2,2-dimethylcyclopropanecarboxylic acid ($Br_2CA$) | AZ2 – Sandy loam | Kd = 0.089 | Koc = 38.6 | Very highly mobile | 1589467 |
| | AZ3 – Clay | Kd = 0.11 | Koc = 46.8 | | |
| | MS – Silty clay loam | Kd = 0.35 | Koc = 43.7 | | |
| | USA – Sandy loam | Kd = 0.61 | Koc = 24.0 | | |
| | MI – Clay loam | Kd = 0.29 | Koc = 11.0 | | |
| Soil column leaching | 96 - 97% of the $^{14}C$ activity remained in the upper 0 - 1 inch layer of the columns with only 1.3 % in the 1 - 2 inch layer. Less than 0.5% of the $^{14}C$ activity recovered was present in any other column segment. No $^{14}C$ was detected in leachate for any of the soils. | | | | 1589469 |

| Process | $T_{1/2}$ or $DT_{50}$ (days) | $DT_{90}$ | Kinetics | Comments | PMRA Reference (original study / foreign review) |
|---|---|---|---|---|---|
| **Terrestrial field studies** | | | | | |
| Lethbridge, Alberta<br>Sandy loam: pH 7.8, 2.2% OM<br>Taber, Alberta<br>Sandy loam: pH 6.9, 1.3% OM | 11.6 – 40.6 | NR | SFO | | [illegible] |
| Hollandale, Minnesota<br>Loamy sand: pH 5.6, 2.2% OM | 19 – 25 | 172 – 1301 | SFO | | [illegible] |
| Sandy clay loam: physico-chemical details of soil not reported | 89 | NR | NR | | [illegible] |
| Ontario<br>Muck soil: physico-chemical properties of soil not reported | 10 – 104 | 33 – 346 | NR | | [illegible] |

## Table 2 Summary of Fate Processes for deltamethrin in the Aquatic Environment

| Process | $T_{1/2}$ or $DT_{50}$ (days) | $DT_{90}$ | Kinetics | Comments | PMRA Reference (original study / foreign review) |
|---|---|---|---|---|---|
| **Abiotic transformation** | | | | | |
| Hydrolysis 25°C, 30 days | pH 5: Stable<br>pH 7: Stable<br>pH 9: 2.5 d | nr | SFO | May be an important route of transformation under alkaline conditions | [illegible] |
| Hydrolysis 25°C, 30 days | pH 9: 31 d | nr | SFO | | [illegible] |
| Aquatic Phototransformation<br>pH 5, 25°C, 30 days | 47.7 | nr | SFO | Not a major route of transformation | [illegible] |
| pH 7, 25°C, 30 days | 64.1 – 87.65 | nr | SFO | Not a major route of transformation | [illegible] |
| **Aerobic transformation** | | | | | |
| 20°C, 84 days<br>TNO water/sediment system: pH 7.1, 12.4% OM | Water phase: 8.2<br>Whole system: 30.9 | Water phase: 13.9<br>Whole system: 456 | SFO<br>IORE | Slightly persistent | [illegible] |
| 20°C, 84 days | | | | | |

| Process | $T_{1/2}$ or $DT_{50}$ (days) | $DT_{90}$ | Kinetics | Comments | PMRA# Reference (original study / foreign review) |
|---|---|---|---|---|---|
| [illegible] water-sediment system pH [illegible], [illegible]% OC | Water phase: [illegible]<br>Whole system: [illegible] | Water phase: [illegible]<br>Whole system: [illegible] | [illegible]<br>[illegible] | Moderately persistent | |
| 20°C, 99 days<br>[illegible] water-sediment system pH [illegible], [illegible] | Water phase: [illegible]<br>Whole system: [illegible]<br>Whole system: [illegible] | Water phase: [illegible]<br>Whole system: [illegible]<br>Whole system: [illegible] | [illegible]<br>[illegible]<br>[illegible] | Non-persistent | [illegible] |
| 20°C, 99 days<br>[illegible] water-sediment system pH [illegible], [illegible] | Water phase: [illegible]<br>Whole system: [illegible]<br>Whole system: [illegible] | Water phase: [illegible]<br>Whole system: [illegible]<br>Whole system: [illegible] | [illegible]<br>[illegible]<br>[illegible] | Non-persistent | |
| [illegible], 100 days<br>Sediment 1 pH [illegible], [illegible]% OC<br>Sediment 2 pH [illegible], [illegible]% OC<br>Sediment 3 pH [illegible], [illegible]% OC | Whole system: [illegible]<br>Whole system: [illegible]<br>Whole system: [illegible] | NR | SFO<br>SFO<br>SFO | Non-persistent to slightly persistent | [illegible] |
| Volatilization from surface water [illegible] | [illegible] | | | | [illegible] |
| **Anaerobic transformation** | | | | | |
| [illegible], 100 days<br>Sediment 1 pH [illegible], [illegible]% OC<br>Sediment 2 pH [illegible], [illegible]% OC<br>Sediment 3 pH [illegible], [illegible]% OC | Whole system: [illegible]<br>Whole system: [illegible]<br>Whole system: [illegible] | NR | SFO<br>SFO<br>SFO | Non-persistent to slightly persistent | [illegible] |
| **Aquatic field studies** | | | | | |
| Outdoor microcosms [illegible] | [illegible] | | | | [illegible] |
| Outdoor microcosms [illegible] | [illegible] | | | | [illegible] |

| Process | $T_{1/2}$ or $DT_{50}$ (days) | $DT_{90}$ | Kinetics | Comments | PMRA Reference (original study / foreign review) |
|---|---|---|---|---|---|
| Outdoor microcosms: 306 days<br>$^{14}$C-deltamethrin (>99%) formulated as emulsifiable concentrate (Decis 25 g a.i./L) | Deltamethrin was applied to microcosm surface (in the 0 – 2 cm water depth via pipette). Initial concentration s of deltamethrin ranged from 1.8 to 2.5 µg/L. Deltamethrin rapidly became distributed in suspended solids, plants, sediment and air; the observed estimated half-life in filtered water was 2 – 4 hours. 38 – 51% of $^{14}$C was detected in suspended solids at 4 hours and 7 – 13% after 24 hours; deltamethrin half-life was 24 – 30 hours. At 306 days, residues in sediment accounted for 88 – 95% of $^{14}$C remaining in ponds; > 50% of the $^{14}$C was present in the unextractable phase. Deltamethrin in sediment reached maximum concentrations at 48 hours post treatment in ponds and decreased to less than 50% of maximum levels by day 5 in pond 1 and 7 – 14 days in pond 2. | | | | 151432 / 2212042 and 2212044 |
| Outdoor microcosms: 55 hours<br>Deltamethrin (as Decis 2.5 EC) | Deltamethrin applied to microcosm surface as a spray; water surface microlayer, sub-surface water and sediment were sampled. Half-life in water surface microlayer and sub-surface water was estimated as ~ 5 minutes and 1 hour, respectively. In sediment, deltamethrin was not detected after 1 day. | | | | 1561435 / 2212040 |
| Outdoor microcosms: 2 years<br>Deltamethrin as Decis 5 EC (50 g/L) | Deltamethrin was applied as a surface spray (aerial application); water surface microlayer, sub-surface water and sediment were sampled. Half-life in water surface microlayer ranged from 1.5 – 5.1 hours. Half-life in sub-surface water ranged from 6.7 – 21 hours; deltamethrin was undetectable in sediment samples at 24 hour and 5 days post treatment. | | | | 1561509 |
| Outdoor microcosms<br>Deltamethrin (as Decis 10 g a.i./L ULV) | Deltamethrin was applied as a ULV spray above pond surface. The average initial concentration of deltamethrin in pond water measured shortly after treatment was 0.45 µg/L and virtually disappeared in 24 hours. 90 – 100% of deltamethrin was adsorbed to suspended solids. A first order half-life of 5.7 hours was reported. | | | | 2214752 |
| Outdoor microcosms: 105 days<br>Deltamethrin (as Deltamethrin EW015) | Deltamethrin was applied as a surface spray three times at an interval of 7 days. SFO $DT_{50}$ in the water column and sediment were 22.4 ad 31.6 days, respectively. The percentage of deltamethrin adsorbed to particulate matter at 4 hours and 1 day after application ranged from 16 to 50%. | | | | 1561600 |

* - $DT_{50}$ / $DT_{90}$ was calculated based on deltamethrin combined with its α-R-isomer.

** - Test systems were treated with several other pyrethroid insecticidal active ingredients.

nr = not reported

## Table 3 Toxicity of Deltamethrin to Non-Target Terrestrial Species

| Organism | Exposure | Test substance | Endpoint value | Effect of concern | Reference |
|---|---|---|---|---|---|
| **Invertebrates** | | | | | |
| Earthworm<br>*Eisenia fetida* | Acute contact | Technical | 14-d $LC_{50}$ > 1290 mg a.i./kg soil<br>14-day NOEC = 447 mg a.i./kg | Mortality | European Commission 2002 (PMRA 2212041) |
| | | | 14-d $LC_{50}$ > 402 mg a.i./kg soil<br>14-day NOEC = 100 mg a.i./kg | Mortality<br>Reduced body weight | PMRA 1561593 |
| Earthworm<br>*Eisenia fetida andrei* | | Deltamethrin (purity not reported) | No toxic effects at 1.7 and 10 mg a.i./kg | | WHO 1990 (PMRA 2212042) |
| Earthworm<br>*Lumbricus terrestris* | | Deltamethrin (purity not reported) | No toxic effects at 12.5 g a.i./ha after 28 days; significant toxic effects observed at 50 – 125 g a.i./ha | | |
| Earthworm<br>*Eisenia fetida* | Chronic | Decis EW 015 (16.42 g a.i./L) | 28-day NOEC = 206.5 g a.i./ha | Adult growth, mortality and reproductive performance | PMRA 1561427 |

| Organism | Exposure | Test substance | Endpoint value | Effect of concern | Reference |
|---|---|---|---|---|---|
| Bee<br>*Apis mellifera* | Acute Contact | Technical | 48-h $LD_{50}$ = 0.0015 µg a.i./bee | Mortality | European Commission 2002 (PMRA 2212041) |
| | | | $LD_{50}$ = 0.051 µg a.i./bee | | WHO 1990 (PMRA 2212042) |
| | | | 48-h $LD_{50}$ = 0.032 µg a.i./bee | | WHO 2012 (PMRA 2369998) |
| | | Decis 25 EC | 48-h $LD_{50}$ = 0.01 µg a.i./bee | | European Commission 2002 (PMRA 2212041) |
| | Acute Oral | Technical | $LD_{50}$ = 0.079 µg a.i./bee | | European Commission 2002 (PMRA 2212041), WHO 1990 (PMRA 2212042), WHO 2012 (PMRA 2369998) |
| | | | 48-h $LD_{50}$ = 0.049 µg a.i./bee | | WHO 2012 (PMRA 2369998) |
| | | Decis 25 EC | 48-h $LD_{50}$ = 0.28 µg a.i./bee | | European Commission 2002 (PMRA 2212041) |
| *Typhlodromus pyri*<br>Predatory mite | Acute – lab test | AE F032640 00 EC03 (purity: 2.76% w/w) | 7-d $LR_{50}$ = 8.10 mg a.i./ha | Mortality | PMRA 1561595 |
| | | AE F032640 00 EC11 (purity: 10.5% w/w) | 7-d $LR_{50}$ = 9.15 mg a.i./ha | | PMRA 1560608 |
| | Acute – Extended lab test | AE F032640 00 EC03 (purity: 2.79% w/w) | Limit test (7.5 g a.i./ha): 58% mortality was observed. | | PMRA 1561655 |
| | | Deltamethrin EC25 (24.9 g a.i./L) | 7-d $LR_{50}$ = 0.058 g a.i./ha | | PMRA 1561656 |
| *Aphidius rhopalosiphi*<br>Parasitic wasp | Acute – lab test | AE F032640 00 EC03 (purity: 2.76% w/w) | 2-d $LR_{50}$ = 0.55 mg a.i./ha | | PMRA 1561610 |
| | | AE F032640 00 EC11 (purity: 10.5% w/w) | 2-d $LR_{50}$ = 1.10 mg a.i./ha | | PMRA 1561612 |
| | Acute – Extended lab test | AE F032640 00 EC11 (purity: 10.5% w/w) | No dose response (16, 14 and 6% mortality at 1.3, 1.7 and 3.1 g a.i./ha); no statistically significant effect on reproductive performance. | Mortality; reproductive performance | PMRA 1561613 |

| Organism | Exposure | Test substance | Endpoint value | Effect of concern | Reference |
|---|---|---|---|---|---|
| *Hypoaspis aculeifer Canestrini*<br>Predatory mite | Acute – lab test | AE F032640 00 EC03 (purity: 2.79% w/w) | 14-d $LR_{50}$ = 18.5 g a.i./ha | Mortality | PMRA 1561642 |
| | | Deltamethrin EC25 (24.9 g a.i./L) | 16-d $LC_{50}$ > 1.78 g a.i./kg dw soil | | PMRA 1561684 |
| | Acute – Extended lab test | AE F032640 00 EC03 (purity: 2.79% w/w) | Limit test (18.5 g a.i./ha). No significant effect on survival or reproductive performance. | | PMRA 1561641 |
| *Chrysoperla carnea*<br>Green lacewing | Acute – lab test | AE F032640 00 EC03 (purity: 2.76% w/w) | $LR_{50}$ > 2 g a.i./ha | Mortality | PMRA 1561620 |
| | | AE F032640 00 EC11 (purity: 10.5% w/w) | 24 and 94% mortality at 0.6 and 2 g a.i./ha, respectively. | | PMRA 1561602 |
| *Pardosa spp.* Wolf spider | | AE F032640 00 EC03 (purity: 2.76% w/w) | Mortality was 16.7, 40, 90, 100 and 100% at 0.1, 0.5, 1.0, 2.0 and 7.5 g a.i./ha. | | PMRA 1561606 |
| Collembola species<br>*Folsomia candida* | | Deltamethrin EC25 (24.9 g a.i./L) | 28-d $LC_{50}$ > 100 mg a.i./kg soil dw | | PMRA 1561426 |
| **Birds** | | | | | |
| Bobwhite quail (*Colinus virginianus*) | Acute oral | Technical (99.3%) | 14-d LD50 > 2250 mg a.i./kg bw | Mortality | European Commission 2002 (PMRA 2212041), UK-PSD 2004 (PMRA 2212040), WHO 2010 (PMRA 2212042) |
| Mallard duck (*Anas Platyrhynchus*) | | Technical (98%) | 14-d LD50 > 4640 mg a.i./kg bw | | European Commission 2002 (PMRA 2212041), WHO 2010 (PMRA 2212042) |
| Bobwhite quail (*Colinus virginianus*) | Dietary | Technical (99.3%) | 5-d $LC_{50}$ > 1307 mg a.i./kg bw/day | | European Commission 2002 (PMRA 2212041) |
| Mallard duck (*Anas Platyrhynchus*) | | | 5-d $LC_{50}$ > 698 mg a.i./kg bw/day | | European Commission 2002 (PMRA 2212041), UK-PSD 2004 (PMRA 2212040). |

| Organism | Exposure | Test substance | Endpoint value | Effect of concern | Reference |
|---|---|---|---|---|---|
| Bobwhite quail<br>*(Colinus virginianus)* | Reproduction | Technical (99.4%) | 22-w NOEC = 450 mg a.i./kg diet<br>(55 mg a.i./kg bw/day) | No effect on reproductive parameters at highest test concentration. | European Commission 2002 (PMRA 2212041), 1143823 |
| Mallard duck<br>*(Anas Platyrhynchus)* | | | 21-w NOEC = 450 mg a.i./kg diet<br>(70 mg a.i./kg bw/day) | | |
| **Mammals** | | | | | |
| Rat | Acute oral<br>(♂ and ♀) | Technical | $LD_{50}$ (in sesame oil) = 128/139 mg/kg bw (♂/♀)<br>$LD_{50}$ (in peanut oil) = 52/30 mg/kg bw (♂/♀)<br>$LD_{50}$ (in PEG) = 67/86 (♂/♀)<br>$LD_{50}$ (in 1% carboxymethyl cellulose) > 5000 mg/kg bw; no mortality | mortality | PMRA 1204881<br>PMRA 1549331<br>PMRA 1549332<br>PMRA 1549327<br>PMRA 1549328<br>PMRA 1549329 |
| Rat (Sprague-Dawley) | Dietary 2-Generation Reproductive Toxicity | Technical (99.7%) | NOEL = 5.5/6.2 mg a.i./kg/day (♂/♀) based on decreased mean pup bw throughout lactation in $F_1$ and $F_2$ pups, and increased mortality in $F_1$ pups (PND 8 and PND 14). | | PMRA 1549367 |
| **Vascular plants** | | | | | |
| Monocot - (oat (*Avena sativa*), corn (*Zea mays*), onion (*Allium cepa*)<br>Dicots – radish (*Raphanus sativus*), cucumber (*Cucumis sativa*), soybean (*Glycine max*), sunflower (*Helianthus annua*) and oil seed rape (*Brassica napus*) | | Seedling emergence (limit test) | Decis Expert EC100 - 99.75 g a.i./L and Decis EC025 - 24.9 g a.i./L<br>No significant adverse effects observed (seedling emergence, plant survival, plant dry weight, phytotoxicity)<br>NOEC = 12.5 g a.i./ha; $EC_{25}$ > 12.5 g a.i./ha | | PMRA 1549504, 1561643 |
| Monocot (oat (*Avena sativa*), corn (*Zea mays*), onion (*Allium cepa*)<br>Dicots – lettuce (*Latuca sativa*), cucumber (*Cucumis sativa*), soybean (*Glycine max*), sunflower (*Helianthus annua*) and oil seed rape (*Brassica napus*) | | Vegetative vigour (limit test) | | | PMRA 1549505, 1549503 |

**Table 4 Mammalian screening level risk assessment using maximum deltamethrin residue values based on the highest seasonal application rate on shelterbelts.**

| | Toxicity (mg ai/kg bw/d) | Feeding Guild (food item) | EDE (mg ai/kg bw) | RQ | LOC Exceeded? |
|---|---|---|---|---|---|
| **Small Mammal (0.015 kg)** | | | | | |
| Acute | 3.00 | Insectivore (small insects) | 3.91 | **1.30** | **Yes** |
| Reproduction | 5.50 | Insectivore (small insects) | 3.91 | 0.71 | **No** |
| **Medium Sized Mammal (0.035 kg)** | | | | | |
| Acute | 3.00 | Herbivore (short grass) | 12.26 | **4.09** | **Yes** |
| Reproduction | 5.50 | Herbivore (short grass) | 12.26 | **2.23** | **Yes** |
| **Large Sized Mammal (1 kg)** | | | | | |
| Acute | 3.00 | Herbivore (short grass) | 6.55 | **2.18** | **Yes** |
| Reproduction | 5.50 | Herbivore (short grass) | 6.55 | **1.19** | **Yes** |

**Table 5. Mammalian screening level risk assessment using maximum deltamethrin residue values based on the highest seasonal application rate on peppers and field corn (15 g a.i./ha × 3 at 5 day intervals).**

| | Toxicity (mg ai/kg bw/d) | Feeding Guild (food item) | EDE (mg ai/kg bw) | RQ | LOC Exceeded? |
|---|---|---|---|---|---|
| **Small Mammal (0.015 kg)** | | | | | |
| Acute | 3.00 | Insectivore (small insects) | 0.96 | 0.32 | No |
| Reproduction | 5.50 | Insectivore (small insects) | 0.96 | 0.17 | No |
| **Medium Sized Mammal (0.035 kg)** | | | | | |
| Acute | 3.00 | Herbivore (short grass) | 3.01 | **1.00** | **Yes** |
| Reproduction | 5.50 | Herbivore (short grass) | 3.01 | 0.55 | No |
| **Large Sized Mammal (1 kg)** | | | | | |
| Acute | 3.00 | Herbivore (short grass) | 1.61 | 0.54 | No |
| Reproduction | 5.50 | Herbivore (short grass) | 1.61 | 0.29 | No |

**Table 6. Mammalian risk assessment using mean deltamethrin residue values based on the maximum single seasonal application rates on shelterbelts (135 g a.i./ha).**

| | Toxicity (mg ai/kg bw/d) | Food Guild (food item) | On field | | Off field | |
|---|---|---|---|---|---|---|
| | | | EDE (mg ai/kg bw) | RQ | EDE (mg ai/kg bw) | RQ |
| **Small Mammal (0.015 kg)** | | | | | | |
| Acute | 3.00 | Insectivore (small insects) | 2.18 | 0.73 | 0.24 | 0.08 |
| | 3.00 | Granivore (grain and seeds) | 0.47 | 0.16 | 0.05 | 0.02 |
| | 3.00 | Frugivore (fruit) | 0.93 | 0.31 | 0.10 | 0.03 |
| **Medium Sized Mammal (0.035 kg)** | | | | | | |
| Acute | 3.00 | Insectivore (small insects) | 1.91 | 0.64 | 0.21 | 0.07 |
| | 3.00 | Insectivore (large insects) | 0.41 | 0.14 | 0.04 | 0.02 |
| | 3.00 | Granivore (grain and seeds) | 0.41 | 0.14 | 0.04 | 0.02 |
| | 3.00 | Frugivore (fruit) | 0.82 | 0.27 | 0.09 | 0.03 |

| | Toxicity (mg ai/kg bw/d) | Food Guild (food item) | On field | | Off field | |
|---|---|---|---|---|---|---|
| | | | EDE (mg ai/kg bw) | RQ | EDE (mg ai/kg bw) | RQ |
| | 3.00 | Herbivore (short grass) | 4.35 | **1.45** | 0.48 | 0.16 |
| | 3.00 | Herbivore (long grass) | 2.44 | 0.81 | 0.27 | 0.09 |
| | 3.00 | Herbivore (forage crops) | 3.75 | **1.25** | 0.41 | 0.14 |
| Reproduction | 5.50 | Insectivore (small insects) | 1.91 | 0.35 | 0.21 | 0.04 |
| | 5.50 | Insectivore (large insects) | 0.41 | 0.07 | 0.04 | 0.01 |
| | 5.50 | Granivore (grain and seeds) | 0.41 | 0.07 | 0.04 | 0.01 |
| | 5.50 | Frugivore (fruit) | 0.82 | 0.15 | 0.09 | 0.02 |
| | 5.50 | Herbivore (short grass) | 4.35 | 0.79 | 0.48 | 0.09 |
| | 5.50 | Herbivore (long grass) | 2.44 | 0.44 | 0.27 | 0.05 |
| | 5.50 | Herbivore (forage crops) | 3.75 | 0.68 | 0.41 | 0.08 |
| **Large Sized Mammal (1 kg)** | | | | | | |
| Acute | 3.00 | Insectivore (small insects) | 1.02 | 0.34 | 0.11 | 0.04 |
| | 3.00 | Insectivore (large insects) | 0.22 | 0.07 | 0.02 | 0.01 |
| | 3.00 | Granivore (grain and seeds) | 0.22 | 0.07 | 0.02 | 0.01 |
| | 3.00 | Frugivore (fruit) | 0.44 | 0.15 | 0.05 | 0.02 |
| | 3.00 | Herbivore (short grass) | 2.33 | 0.78 | 0.26 | 0.09 |
| | 3.00 | Herbivore (long grass) | 1.31 | 0.44 | 0.14 | 0.05 |
| | 3.00 | Herbivore (forage crops) | 2.00 | 0.67 | 0.22 | 0.07 |
| Reproduction | 5.50 | Insectivore (small insects) | 1.02 | 0.19 | 0.11 | 0.02 |
| | 5.50 | Insectivore (large insects) | 0.22 | 0.04 | 0.02 | 0.01 |
| | 5.50 | Granivore (grain and seeds) | 0.22 | 0.04 | 0.02 | 0.01 |
| | 5.50 | Frugivore (fruit) | 0.44 | 0.08 | 0.05 | 0.01 |
| | 5.50 | Herbivore (short grass) | 2.33 | 0.42 | 0.26 | 0.05 |
| | 5.50 | Herbivore (long grass) | 1.31 | 0.24 | 0.14 | 0.03 |
| | 5.50 | Herbivore (forage crops) | 2.00 | 0.36 | 0.22 | 0.04 |

## Table 7 Toxicity of Deltamethrin to Non-Target Aquatic Species

| Organism | Exposure | Test Substance | Endpoint Value (µg ai/L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| **Freshwater invertebrates** | | | | | |
| Water flea (*Daphnia magna*) | acute, 48 hr | deltamethrin | $EC_{50}$ = 9 | Mortality | UK-PSD 2004 (PMRA 2212040) |
| | | deltamethrin | $EC_{50}$ = 3.5<br>NOEC = 1.8 | | |
| | acute, 48 hr | deltamethrin, 97% ai | $EC_{50}$ = 0.56 (measured)<br>NOEC = 0.11 | | European Commission 2002 (PMRA 2212041) |
| | acute, 48 hr | $Br_2CA$, 98.8% ai | $EC_{50}$ > 100,000<br>NOEC = 100,000 | | (PMRA 1549484) |
| | acute, 48 h | IS-002A, deltamethrin 25.4% ai | $EC_{50}$ = 0.11<br>NOEC = 0.082 | | European Commission 2002 (PMRA 2212041) |
| | acute, 48 h | Deltamethrin, 98.5% a.i. | $EC_{50}$ = 0.075 | | WHO 2010 (PMRA 2273250) |

| Organism | Exposure | Test Substance | Endpoint Value (µg ai/L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| | acute 48 h | Deltamethrin | $EC_{50}$ = 0.021 (6 – 24 h old)<br>$EC_{50}$ = 0.029 (48 – 72 h old) | | Xiu *et al.* 1989 (PMRA 2281469) |
| | acute 48 h | Deltamethrin, 99.8 a.i. | $LC_{50}$ = 1.6 | | Barata *et al.* 2006 (PMRA 2281502) |
| | acute, 48 h | Deltamethrin<br>Decis 62.5 EC - 7.11% ai | $EC_{50}$ 0.29 (0.22-0.38); NOEC = 0.064 | | Putt, M.A. 1993 (PMRA 1561536) |
| | acute, 48 h | deltamethrin, 99.9% ai | With the presence of 2.2 mg/L of dissolved organic carbon = $EC_{50}$ 0.05 (0.03-0.09)<br>With the presence of 4.5 mg/L of dissolved organic carbon = $EC_{50}$ 1.01 (0.65-1.61)<br>With the presence of 10.1 mg/L of dissolved organic carbon = $EC_{50}$ 0.85 (0.55-1.30) | | Day, 1991 (PMRA 2275726) |
| | Acute 96 h | Deltamethrin<br>(Decis EC 25 g a.i./L) | $LC_{50}$ = 0.0250 (95% CI 0.008 – 0.05) | | Beketov 2004 (PMRA 2276776) |
| | acute, 48 h | deltamethrin, > 95% ai | Result of two bioassays:<br>$EC_{50}$ = 0.07<br>$EC_{50}$ = 0.05 | | Day and Maguire, 1990 (PMRA 2275877) |
| | acute, 48 h | 3-phenoxybenzyl alcohol (PBalc) | $EC_{50}$ > 50 | | |
| | acute, 48 h | 3-phenoxybenzaldehyde (PBald) | $EC_{50}$ > 50 | | |
| | acute, 48 h | 3-phenoxybenzoic acid (PBacid) | $EC_{50}$ > 50 | | |
| | acute, 48 h | Cis-3-(2,2-dibromovinyl)-2,2-dimethylcyclopropane carboxylic acid (DBCA) | $EC_{50}$ > 50 | | |
| *Daphnia spinulata* | acute, 48 h | deltamethrin, 99% ai | 50% mortality at 1.25 µg/L; an $LC_{50}$ was not reported. | | Alberdi *et al.* 1996 PMRA 227527 |
| *Ceriodaphnia* cf. *dubia* | acute, 48 h | Deltamethrin, 98% ai | Lab water: $LC_{50}$ = 0.021, 0.020, 0.029 and 0.020<br>River water: $LC_{50}$ = 0.083, 0.088<br>$LC_{50}$ values are from different experiments with varying salinities (~200 – 750 µS/cm) | | Thomas *et al.* 2008 PMRA 2284576 |
| *Moina micrura*<br>Cladoceran species | acute, 48 h | Deltamethrin technical | 100% mortality at lowest test concentration (4.4 µg a.i./L) | | Lahr *et al.* 2000<br>(PMRA 2281464) |
| *Diaphanosoma excisum*<br>Cladoceran species | acute, 48 h | | | | |
| *Moina micrura*<br>Cladoceran species | 5 d Chronic | | NOEC = 0.89<br>( | Reduced growth rate at 2.2 µg a.i./L | |

| Organism | Exposure | Test Substance | Endpoint Value (µg ai/L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| *Hyalella azteca* | 10-d Chronic | Deltamethrin technical | LC50 = 3.8 ng/g dry sediment Sediment = 1.1% OC<br>LC50 = 10.0 ng/g dry sediment Sediment = 1.4% OC | Mortality | Amweg *et al.* 2005 (PMRA 2281501) |
| *Paratya australiensis* Freshwater shrimp | Acute, 96 h (semi-static) | Deltamethrin, 98% ai | Fish culture water: LC50 = 0.052, 0.057<br>River water LC50 = 0.065<br>LC50 values are from different experiments with varying salinities (~200 – 750 µS/cm) | | Thomas et al. 2008 (PMRA 2284576) |
| *D. magna* | Chronic | Deltamethrin technical | MATC = 6800 - 13000 | Not reported | UK PSD 2004 (PMRA 2212040) |
| | 21 d Chronic | Deltamethrin technical | NOEC = 0.0041 (measured) | Reduced growth (measured as total body length) | European Commission 2002 (PMRA 2212041) |
| **Aquatic insects** | | | | | |
| *Gammarus fasciatus* | Acute, 96 h | Decis EC | LC50 = 0.00031 (measured)<br>LC50 = 0.0032<br>LC50 = 0.003 | Mortality | European Commission 2002 (PMRA 2212041) |
| *Gammarus pulex* | Acute, 96 h | Deltamethrin technical | LC50 = 0.068 (0.061 – 0.075) | | Adam *et al.* 2010 (PMRA 2281496) |
| *Gammarus fossarum* | | | LC50 = 0.035 (0.025 – 0.046) | | |
| *A. aquaticus* | Acute, 96 h | Decis EC | 96 h LC50 = 0.0051 | | European Commission 2002 (PMRA 2212041) |
| Scud *Gammarus pulex* | Acute 48 h | Deltamethrin (EC 25 g a.i./L) | LC50 = 0.03 | | WHO 1990 (PMRA 2212042) |
| Blackfly *(Simulium vittatum)* | Acute, 1 h (flow-through) | Deltamethrin (2.5% EC) | 24 h LC50 = 0.9 | | |
| Mayfly *(Baetis parvus)* | | | 24 h LC50 = 0.8 | | |
| Caddisfly *(Hydropsyche californica)* | | | 24 h LC50 = 0.8 | | |
| Mayfly larvae *Cloeon dipterum* | Acute 96 h | Deltamethrin (Decis EC 25 g a.i./L) | LC50 = 0.0050 (95% CI 0.0036 – 0.0069) | | Beketov 2004 (PMRA 2276776) |
| Mayfly larvae *Caenis miliaria* | | | LC50 = 0.0088 (95% CI 0.0067 – 0.0126) | | |
| Damselfly larvae *Lestes sponsa* | | | LC50 = 0.0145 (95% CI 0.0110 – 0.0190) | | |

| Organism | Exposure | Test Substance | Endpoint Value (µg a.i./L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| Chironomid larvae<br>*[illegible]* | | | $LC_{50}$ = [illegible] | | |
| Mosquito larvae<br>*Culex quinquefasciatus* | Acute 24 h | [illegible] technical | $LC_{50}$ = [illegible] | | [illegible] |
| Mosquito pupae<br>*Culex quinquefasciatus* | | | $LC_{50}$ = [illegible] | | |
| Mosquito larvae<br>*Culex tarsalis* | | | $LC_{50}$ = [illegible] | | |
| Mosquito pupae<br>*Culex tarsalis* | | | $LC_{50}$ = [illegible] | | |
| Mosquito larvae<br>*Culiseta inornata* | | | $LC_{50}$ = [illegible] | | |
| Mosquito pupae<br>*Culiseta inornata* | | | $LC_{50}$ = [illegible] | | |
| Mosquito larvae<br>*Aedes nigromaculis* | | | $LC_{50}$ = [illegible] | | |
| Mosquito pupae<br>*Aedes nigromaculis* | | | $LC_{50}$ = [illegible] | | |
| Mosquito larvae<br>*Aedes taeniorhynchus* | | | $LC_{50}$ = [illegible] | | |
| Mosquito pupae<br>*Aedes taeniorhynchus* | | | $LC_{50}$ = [illegible] | | |
| Mosquito larvae<br>*Psorophora columbiae* | | | $LC_{50}$ = [illegible] | | |

| Organism | Exposure | Test Substance | Endpoint Value (µg a.e./L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| Mosquito pupae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito larvae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito pupae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito larvae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito pupae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito larvae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito larvae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito pupae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito larvae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito pupae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito larvae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Mosquito pupae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Midge larvae<br>[illegible] | | | LC$_{50}$ = [illegible] | | |
| Midge larvae<br>[illegible] | | | LC$_{50}$ = [illegible]<br>LC$_{50}$ = [illegible]<br>LC$_{50}$ = [illegible] | | |

| Organism | Exposure | Test Substance | Endpoint Value (µg ai/L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| Midge larvae *Procladius* spp. |  |  | $LC_{50}$ = 0.07<br>$LC_{90}$ = 0.029 |  |  |
| Midge larvae *Tanytarsus* spp. |  |  | $LC_{90}$ = 0.016 |  |  |
| Midge larvae *Tanypus grodhausi* |  |  | $LC_{90}$ = 0.11 |  |  |
| Midge larvae *Cricotopus* spp. |  |  | $LC_{90}$ = 0.11 |  |  |
| Midge larvae *Dicrotendipes californicus* |  |  | $LC_{90}$ = 2.10 |  |  |
| *Chironomus riparius* | 28 d Chronic | Deltamethrin | NOEC = 0.01 | Adult emergence | European Commission 2002 (PMRA 2212041) |
| **Freshwater mussels** |  |  |  |  |  |
| Freshwater mussel *Anodonta cygnea* | Acute 96 h (static) | Deltamethrin (0.12% ULV) | $LC_{50}$ = 12.0 | Mortality | WHO 1990 (PMRA 2212042) |
| Freshwater mussel *Anodonta anatina* |  |  | $LC_{50}$ = 23.4 |  | WHO 1990 (PMRA 2212042) |
| Freshwater mussel *Unio pictorum* |  |  | $LC_{50}$ = 7.0 |  | WHO 1990 (PMRA 2212042) |
| **Freshwater fish** |  |  |  |  |  |
| Bluegill sunfish (*Lepomis macrochirus*) | Acute, 96 h (flow-through) | Deltamethrin technical | $LC_{50}$ = 1.2 | Mortality | UK-PSD 2004 (PMRA 2212040) |
|  | Acute, 96 h (static) |  | $LC_{50}$ = 1.4<br>NOEC = 0.41 |  |  |
|  | Acute, 96 h (flow-through) | Deltamethrin, 98.5% a.i. | 96 h $LC_{50}$ = 0.73<br>NOEC = 0.29 |  | WHO 2010 (PMRA 2275250) |
| Pumpkinseed sunfish (*Lepomis gibbosus*) | Acute, 96 h (flow-through) | Deltamethrin technical | $LC_{50}$ = 0.58 |  | WHO 1990 (PMRA 2212042) |
|  | Acute, 96 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 0.87 |  |  |
| Brown bullhead (*Ictalurus nebulosus*) | Acute, 96 h (flow-through) | Deltamethrin technical | $LC_{50}$ = 1.2 |  |  |
|  | Acute, 96 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 2.3 |  | WHO 1990 (PMRA 2212042) |

| Organism | Exposure | Test Substance | Endpoint Value (µg ai/L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| Channel catfish (*Ictalurus punctatus*) | Acute, 96 h (flow-through) | Deltamethrin technical | $LC_{50}$ = 0.63 | | |
| European catfish (*Silurus glanis L.*) | Acute, 96 h (static) | Decis 2.5 EC (2.5% a.i.) | $LC_{50}$ = 0.69 | | Köprücü *et al.* 2006 (PMRA 2285978) |
| Freshwater catfish (*Clarias gariepinus*) | Acute, 96 h (static) | K-Obiol 2.5 WP | $LC_{50}$ = 0.1 | | Kaviraj and Datta 2003 (PMRA 2287540) |
| Rainbow trout (*Oncorhynchus mykiss*) | Acute, 96 h (static) | Deltamethrin | $LC_{50}$ = 0.39 | | UK-PSD 2004 (PMRA 2212040) |
| | | | $LC_{50}$ = 0.91<br>NOEC = 0.2 | | |
| | Acute, 96 h (semi-static) | Decis EW50 (50 g a.i./L) | Juvenile: $LC_{50}$ = 1.0 | | Velisek *et al.* 2007 (PMRA 2281478) |
| | Acute, 96 h (flow-through) | Deltamethrin, 98.5% a.i. | $LC_{50}$ = 0.69 | | WHO 2010 (PMRA 2275250) |
| | Acute, 96 h (static) | Deltamethrin (IS-002A) | $LC_{50}$ = 0.26 (measured) | | European Commission 2002 (PMRA 2212041) |
| | Acute, 96 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 2.2 | | WHO 1990 (PMRA 2212042) |
| | | | $LC_{50}$ = 0.5 | | NRCC 1986 (PMRA 2212044) |
| | | $Br_2CA$, 98.8% ai | $LC_{50}$ = 100,000<br>NOEC = 18,000 | | PMRA 1549489 |
| | Sub Chronic, 28 d | Deltamethrin | NOEC < 0.032 | | European Commission 2002 (PMRA 2212041) |
| Bleak (*Alburnus alburnus*) | Acute, 96 h (static) | Deltamethrin technical | $LC_{50}$ = 0.69 | Mortality | WHO 1990 (PMRA 2212042) |
| | | Deltamethrin (ULV 1 g a.i./L) | $LC_{50}$ = 82 | | |
| Zebra fish (*Brachydanio rerio*) | Acute, 96 h (flow-through) | Deltamethrin technical | $LC_{50}$ = 2.0 | | |
| | 35 d ELS | Deltamethrin, > 98% a.i. | 35 d $LC_{50}$ = 0.52 (0.46 – 0.58)<br>NOEC = 0.5 (based on hatching success) | Mortality<br>Hatching success | Gorge and Nagel 1990 (PMRA 2287547) |
| Desert pupfish *Cyprinodon macularius* | Acute, 48 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 0.6 | Mortality | WHO 1990 (PMRA 2212042) |
| Common carp (*Cyprinus carpio*) | Acute, 96 h (flow-through) | Deltamethrin technical | $LC_{50}$ = 1.84 | | |
| | Acute, 96 h (static) | | $LC_{50}$ = 0.86 | | |

| Organism | Exposure | Test Substance | Endpoint Value (µg ai/L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| | Acute, 96 h (flow-through) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 0.65 | | |
| | Acute, 96 h (static) | Deltamethrin (ULV 1 g a.i./L) | $LC_{50}$ = 210 | | |
| | Acute, 24 h (static) | Deltamethrin (purity not reported) | 10 day old carp larvae:<br>$LC_{50}$ ranged between 2 - 8 | | Ghillebaert *et al.* 1996 (PMRA 2284371) |
| Mosquito Fish (*Gambusia affinis*) | Acute, 48 h (flow-through) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 1.0 | | WHO 1990 (PMRA 2212042) |
| Golden orfe (*Idus idus melanotus*) | Acute, 96 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 1.2 | | |
| Guppy (*Lebistes reticulatus*) | Acute, 96 h (flow-through) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 1.8 | | |
| Guppy (*Poecilia reticulata*) | Acute, 48 h (static) | Deltamethrin, 98% a.i. | $LC_{50}$ = 5.13 (3.33 – 6.70) | | Viran et al. 2003 (PMRA 2285980) |
| | Acute, 24 h (static) | Deltamethrin technical<br>K-Othrine 2.5% Flow | $LC_{50}$ = 16<br>$LC_{50}$ = 18000 | | Mittall *et al.* 1994 (PMRA 2294355) |
| Nilem carp - tropical fish (*Osteochilus hasselti*) | Acute, 96 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 1.2 | | WHO 1990 (PMRA 2212042) |
| Jawa carp - tropical fish (*Puntius gonionotus*) | Acute, 96 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 0.87 | | |
| European bitterling *Rhodeus sericeus amarus* | Acute, 96 h (static) | Deltamethrin technical | $LC_{50}$ = 1.12 | | |
| | Acute, 96 h (static) | Deltamethrin (ULV 1 g a.i./L) | $LC_{50}$ = 140 | | |
| Brown trout *Salmo trutta* | Acute, 48 h (flow-through) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 4.7 | | |
| *Sarotherodon mossambicus* - tropical fish | Acute, 96 h (flow-through) | Deltamethrin technical | $LC_{50}$ = 3.5 | | |
| | Acute, 96 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 2.0 | | |
| *Tilapia mossambica* - tropical fish | Acute, 48 h (flow-through) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 0.8 | | |
| Nile tilapia *Oreocromis niloticus* | Acute, 96 h (static) | Deltamethrin, 98% a.i. | Larvae: $LC_{50}$ = 1.17 (0.85 – 1.52)<br>Fry: $LC_{50}$ = 1.70 (1.42 – 1.96) | | Benli *et al.* 2009 (PMRA 2287544) |
| | Acute, 96 h (semi-static) | 2.5% w/v EC | $LC_{50}$ = 14.5 (14 – 14.9) | | Golow and Godzi 1994 (PMRA 2284363) |

| Organism | Exposure | Test Substance | Endpoint Value (µg ai/L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| Eastern rainbow fish<br>*Melamotaenia duboulayi* | Acute, 96 h<br>(semi-static) | Deltamethrin, 98% a.i. | Fish culture water: $LC_{50}$ = 0.212, 0.232, 0.135, 0.253<br>River water: $LC_{50}$ = 0.187<br>$LC_{50}$ values are from different experiments with varying salinities (~200 – 750 µS/cm) | Mortality | Thomas *et al.* 2008 (PMRA 2284376) |
| **Amphibians** | | | | | |
| Common toad (larvae)<br>*Bufo bufo* | Acute, 96 h | Deltamethrin<br>(EC 25 g a.i./L) | $LC_{50}$ = 0.93 | Mortality | WHO 1990 (PMRA 2212042) |
| South American toad<br>Bufo arenarum | Acute, 96 h<br>(semi-static) | Deltamethrin, 98% a.i. | Larval stages 26 – 27: $LC_{50}$ = 4.37 (3.72 – 5.19)<br>Larval stages 28 – 30: $LC_{50}$ = 4.5 (4.02 – 5.00) | | Salibián 1992 (PMRA 2287551) |
| **Algae and aquatic plants** | | | | | |
| Green algae<br>*Pseudokirchneriella subcapitata* | Acute, 96 h | Deltamethrin, LX 165-09 | Uncertain value | | European Commission 2002 (PMRA 2212041) |
| | | EC, 100 g a.i./L | $EC_{50}$ = 17800<br>$EC_{50}$ > 72600 | growth rate<br>biomass | PMRA 1564586 |
| | | 15-002A (25 g a.i./L) | $EC_{50}$ = 1700 (1590 – 4300)<br>NOEC = 610 | growth rate | PMRA 1561533 |
| | | Deltamethrin technical | Limit test: $EC_{50}$ > 620 | No reduction in cell density | UK-PSD 2004 (PMRA 2212040) |
| Green algae<br>*Chlorella vulgaris* | | | Limit test: $EC_{50}$ > 9100 | No reduction in growth rate | |
| Cyanobacteria<br>*Cylindrospermopsis raciborskii*<br>Green algae<br>*Monoraphidium* sp | Acute, 48 h | Deltamethrin technical | NOEC ≥ 443 | Chlorophyll a | Leboulanger *et al.* 2009<br>(PMRA 2281464) |
| **Mesocosms** | | | | | |
| Outdoor mesocosms: 145 days; $^{14}$C-deltamethrin (> 96%) formulated as emulsifiable concentrate (Decis 25 g a.i./L) | $^{14}$C deltamethrin was mixed into the upper 25cm water layer of a 1m water column. $DT_{50}$ < 17 hours in water column. Most sensitive population: *Chaoborus* larvae (macrophyte phase) NOEC < 1.0 ng a.i./L. Recovery 14 – 28 days at 1.0 to 180 mg a.i./L. | | | NOEC based on taxonomic richness = 18 ng a.i./L | European Comission 2002<br>(PMRA 2212041; 1561624) |

| Organism | Exposure | Test Substance | Endpoint Value (µg ai/L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| Outdoor mesocosms: 105 days. Deltamethrin (as Deltamethrin EW015) | Deltamethrin was applied as a surface spray three times at an interval of 7 days. Most sensitive population: *Chaoborus* larvae NOEC = 4.8 ng a.i./L. Recovery = 7 weeks after last application for all taxa. | | | NOEC (community level) = 51 ng a.i./L | PMRA 1561680 |
| **Aquatic vascular plants** | | | | | |
| Toxicity data for freshwater aquatic vascular plants was not available. | | | | | |
| **Marine/estuarine invertebrates** | | | | | |
| Marine mysid<br>*Mysidopsis bahia* | Acute, 96 h<br>(static renewal) | Deltamethrin technical | $LC_{50}$ = 0.0046 (0.0037 mean measured)<br>NOEC = 0.0013 (0.0006 mean measured) | Mortality | UK-PSD 2004 (PMRA 2212040) |
| | | IS-002A (24.8 g a.i./L) | $LC_{50}$ = 0.0031 (0.0017 mean measured)<br>NOEC < 0.0008 (0.0006 mean measured) | | PMRA 1561532 |
| | Acute, 96 h<br>(flow-through) | Decis 62.5 EC (61.5 g a.i./L; 7.11%) | $LC_{50}$ = 0.0059<br>NOEC = 0.005<br>(based on mean measured) | | PMRA 1561535 |
| | Chronic, 35 d life cycle | [Benzyl-$^{14}$C] Deltamethrin (radiopurity > 99%) | NOEC = 0.00073<br>(based on mean measured) | Reproduction | PMRA 2227762 |
| Pink shrimp<br>*Penaeus duorarum* | Acute 96 h | Deltamethrin<br>(EC 25 g a.i./L) | $EC_{50}$ = 0.35 | Mortality | WHO 1990 (PMRA 2212042) |
| Eastern Oyster *Crassostrea virginica* | Acute, 96 h<br>(flow-through) | Deltamethrin technical | $EC_{50}$ = 8.2<br>NOEC = 3.4 | | UK-PSD 2004 (PMRA 2212040) |
| | | IS-002A (24.8 g a.i./L) | $EC_{50}$ = 35 (15 mean measured)<br>NOEC = 11 (4.0 mean measured)<br>(based on reduced shell growth) | | PMRA 1561450 |
| | | Decis 62.5 EC (61.5 g a.i./L; 7.11%) | $EC_{50}$ = 900<br>NOEC = 240<br>(based on reduced shell growth; mean measured) | | PMRA 1561538 |
| | Acute 96 h | Deltamethrin<br>(EC 25 g a.i./L) | $LC_{50}$ = 12.0 | | WHO 1990 (PMRA 2212042); NRCC 1986 (PMRA 2212044) |
| Fiddler crab<br>*Uca pugilator* | Acute 96 h | Deltamethrin<br>(EC 25 g a.i./L) | $EC_{50}$ = 1.1 | | |
| Northern lobster<br>*Homarus americanus* | Acute 96 h | Deltamethrin | $EC_{50}$ = 0.0014 | | |
| Northern lobster<br>*Homarus Americanus* | Acute 96 h (static) | Decis (50 g a.i./L) | $LC_{50}$ = 0.0049 (0.0032 – 0.0075) | | Fairchild *et al.* 2010 (PMRA 2295056) |
| | | Alphamax (10 g a.i./L) | $LC_{50}$ = 0.0037 (0.0023 – 0.0062) | | |
| | 1 hour static | | $LC_{50}$ = 0.0365 (0.0250 – 0.0533) | | |

| Organism | Exposure | Test Substance | Endpoint Value (µg ai/L) | Effect of concern | Reference |
|---|---|---|---|---|---|
| (Stage III larval state) | 16 d semi-static | | $LC_{50}$ = 0.0045 (0.0037 – 0.0054) | | |
| Sand shrimp *Crangon septemspinosa* | 14 d semi-static | | $LC_{50}$ = 0.0238 (0.0191 – 0.0297) | | |
| Marine amphipod *Eohaustorius estuarius* | 96 h (static) | | $LC_{50}$ = 0.0017 (0.0003 – 0.005) | | |
| **Marine/Estuarine Fish** | | | | | |
| Sheepshead minnow *(Cyprinodon variegatus)* | Acute, 96 h (flow-through) | Deltamethrin | $LC_{50}$ = 0.48 (measured)<br>NOEC = 0.35 | Mortality | UK-PSD 2004 (PMRA 2212040) |
| | Acute, 96 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 0.9 | | WHO 1990 (PMRA 2212042) |
| | Acute, 96 h (flow-through) | Deltamethrin (Decis 62.5 EC; 61.5 g a.i./L, 7.11%) | $LC_{50}$ = 4.5 (3.1 – 6.2; mean measured) | | PMRA 1561499 |
| Atlantic salmon *Salmo salar* | Acute, 96 h (flow-through) | Deltamethrin | $LC_{50}$ = 1.97 | | WHO 1990 (PMRA 2212042) |
| | Acute, 96 h (static) | Deltamethrin (EC 25 g a.i./L) | $LC_{50}$ = 0.59 | | |

## Table 8 Spray drift risk assessment for non-target aquatic organisms

| Organism | Exposure | Species | Endpoint reported (µg ai/L) | Endpoint for RA[1] (µg ai/L) | Use Scenario | Application rate [2] (g ai/ha) | EEC (µg ai/L) | RQ | LOC exceeded? |
|---|---|---|---|---|---|---|---|---|---|
| Freshwater Invertebrate | Acute | 32 invertebrate: planktonic (2), aquatic insects (27) and mollusks (3). | HD5 = 0.0036 | 0.0036 | field sprayer | 3.25 (soybean) | 0.04 | **11** | Yes |
| | | | | | | 135 (shelterbelt) | 1.86 | **516** | Yes |
| | Chronic | Daphnid (*Daphnia magna*) | NOEC = 0.0041 | 0.0041 | field sprayer | 3.25 (soybean) | 0.04 | **9.8** | Yes |
| | | | | | | 135 (shelterbelt) | 1.86 | **453** | Yes |
| Freshwater fish | Acute | 23 species of freshwater fish | HD5 = 0.22 | 0.22 | field sprayer | 3.25 (soybean) | 0.04 | 0.2 | No |
| | | | | | | 135 (shelterbelt) | 1.86 | **9.3** | Yes |
| | Chronic | Rainbow trout | 28 d NOEC < 0.032 | 0.032 | field sprayer | 3.25 (soybean) | 0.04 | **1.3** | Yes |
| | | | | | | 135 (shelterbelt) | 1.86 | **58** | Yes |
| Amphibian | Acute | Common toad larvae (*Bufo Bufo*) | 96 h $LC_{50}$ = 0.93 | 0.09 | field sprayer | 3.25 (soybean) | 0.23 | **2.6** | Yes |
| | | | | | | 135 (shelterbelt) | 9.9 | **110** | Yes |
| | Chronic | Surrogate fish: | NOEC < | 0.032 | field sprayer | 3.25 (soybean) | 0.23 | **7.2** | Yes |

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Rainbow trout | 0.032 | | | 135 (shelterbelt) | 9.9 | **309** | Yes |
| Freshwater aquatic community | Chronic | NOEC based on taxonomic richness = 18 ng a.i./L | NOEC = 0.018 | 0.018 | field sprayer | 3.25 (soybean) | 0.04 | **2.2** | Yes |
| | | | | | | 135 (shelterbelt) | 1.86 | **103** | Yes |
| Marine /estuarine invertebrate | Acute | 7 invertebrate species | HC$_5$ = 0.00012 | 0.00012 | field sprayer | 3.25 (soybean) | 0.04 | **333** | Yes |
| | | | | | | 135 (shelterbelt) | 1.86 | **15500** | Yes |
| Marine /estuarine fish | Acute | Sheepshead minnow (*Cyprinodon variegatus*) | 96 h LC$_{50}$ = 0.48 | 0.048 | field sprayer | 3.25 (soybean) | 0.04 | 0.8 | No |
| | | | | | | 135 (shelterbelt) | 1.86 | **39** | Yes |
| Plant | No data available | | | | | | | | |

1- Endpoints used in the acute exposure risk assessment (RA) are derived by dividing the EC$_{50}$, LC$_{50}$ from the appropriate laboratory study by a factor of two (2) for aquatic invertebrates and plants, and by a factor of ten (10) for fish and amphibians.
The HD$_5$ is the 5th percentile of the species sensitivity distribution for the LC$_{50}$ or NOEC at 50% confidence intervals.
2 - The assessment of potential risk from drift was assessed for the minimum single ground application for soybean (3.25 g a.i./ha) and the maximum single application rate for shelterbelts (135 g a.i./ha); these application rates cover the full range of application rates and application methods.
3 - The maximum amount of spray that is expected to drift 1m downwind from the application site during spraying using field sprayer application method was determined based on a fine spray droplet size, 11%.
Bolded values indicates an exceedance of the level of concern (RQ = 1).

## Table 9 PRZM/EXAMS runoff modelling results (µg a.i./L) for deltamethrin in water bodies 0.8 m and 0.15 m deep, excluding spray drift.

| Depth of water body | Peak | 96-hour | 21-day | 60-day | 90-day | Yearly |
|---|---|---|---|---|---|---|
| **Lowest single ground application rate: 1 × 3.25 g a.i./ha on soybean** | | | | | | |
| **15 cm** | 0.0737 | 0.0154 | 0.0053 | 0.0022 | 0.0016 | 0.0006 |
| **80 cm** | 0.0139 | 0.0032 | 0.0014 | 0.0008 | 0.0006 | 0.0003 |
| **Highest seasonal ground application rate: 8 × 10 g a.i./ha @ 10d on broccoli** | | | | | | |
| **15 cm** | 0.9907 | 0.1430 | 0.0427 | 0.0271 | 0.0208 | 0.0088 |
| **80 cm** | 0.1874 | 0.0297 | 0.0120 | 0.0094 | 0.0078 | 0.0055 |
| **Highest seasonal aerial application rate: 1 × 15 g a.i./ha on corn** | | | | | | |
| **15 cm** | 0.3084 | 0.0431 | 0.0112 | 0.0051 | 0.0041 | 0.0017 |
| **80 cm** | 0.0581 | 0.0088 | 0.0028 | 0.0017 | 0.0016 | 0.0010 |
| **Highest seasonal airblast application rate: 3 × 12.5 kg a.i./ha @ 7d on apples** | | | | | | |
| **15 cm** | 0.0290 | 0.0045 | 0.0010 | 0.0004 | 0.0003 | 0.0001 |
| **80 cm** | 0.0054 | 0.0009 | 0.0002 | 0.0001 | 0.0001 | 0.0001 |

*Solubility was increased to 0.02 mg/L, for all scenarios, to make the model run.

## Table 10 Refined risk assessment of deltamethrin for aquatic organisms from predicted run-off

| Organism | Exposure | Species | Endpoint reported (µg ai/L) | Endpoint for RA* (µg ai/L) | Use Rate** (g ai/ha) | EEC*** (µg ai/L) | RQ | LOC exceeded? |
|---|---|---|---|---|---|---|---|---|
| **Freshwater Species** | | | | | | | | |
| Invertebrate[1] | Acute | 32 invertebrate: planktonic (2), aquatic insects (27) and mollusks (3). | $HD_5 = 0.0036$ | 0.0036 | 3.25 (soybean, ground) | 0.014 | **3.8** | **Yes** |
| | | | | | 10 (x8, broccoli, ground) | 0.19 | **53** | **Yes** |
| | | | | | 12.5 (3x, apples, airblast) | 0.005 | **1.4** | **Yes** |
| | | | | | 15 (corn, aerial) | 0.056 | **16** | **Yes** |
| | Chronic | Daphnid (*Daphnia magna*) | 21d NOEC = 0.0041 | 0.0041 | 3.25 (soybean, ground) | 0.001 | 0.24 | No |
| | | | | | 10 (x8, broccoli, ground) | 0.012 | **2.9** | **Yes** |
| | | | | | 12.5 (3x, apples, airblast) | 0.0002 | < 0.1 | No |
| | | | | | 15 (corn, aerial) | 0.003 | 0.7 | No |
| Fish[1] | Acute | 23 species of freshwater fish | $HD_5 = 0.22$ | 0.22 | 3.25 (soybean, ground) | 0.003 | < 0.1 | No |
| | | | | | 10 (x8, broccoli, ground) | 0.03 | 0.2 | No |
| | | | | | 12.5 (3x, apples, airblast) | 0.0009 | < 0.1 | No |
| | | | | | 15 (corn, aerial) | 0.009 | < 0.1 | No |
| | Chronic | Rainbow trout | 28 d NOEC < 0.032 | 0.032 | 3.25 (soybean, ground) | 0.001 | < 0.1 | No |
| | | | | | 10 (x8, broccoli, ground) | 0.012 | 0.4 | No |
| | | | | | 12.5 (3x, apples, airblast) | 0.0002 | < 0.1 | No |
| | | | | | 15 (corn, aerial) | 0.003 | < 0.1 | No |
| Amphibian[1] | Acute | Common toad larvae (*Bufo Bufo*) | 96 h $LC_{50}$ = 0.93 | 0.09 | 3.25 (soybean, ground) | 0.02 | 0.2 | No |
| | | | | | 10 (x8, broccoli, | 0.14 | **1.6** | **Yes** |

| Organism | Exposure | Species | Endpoint reported (µg ai/L) | Endpoint for RA* (µg ai/L) | Use Rate** (g ai/ha) | EEC*** (µg ai/L) | RQ | LOC exceeded? |
|---|---|---|---|---|---|---|---|---|
| | | | | | ground) | | | |
| | | | | | 12.5 (3 x, apples, airblast) | 0.005 | < 0.1 | No |
| | | | | | 15 (corn, aerial) | 0.04 | 0.4 | No |
| | Chronic | Surrogate fish: Rainbow trout | 28 d NOEC = 0.032 | 0.032 | 3.25 (soybean, ground) | 0.005 | 0.2 | No |
| | | | | | 10 (x8, broccoli, ground) | 0.04 | **1.3** | **Yes** |
| | | | | | 12.5 (3 x, apples, airblast) | 0.001 | < 0.1 | No |
| | | | | | 15 (corn, aerial) | 0.01 | 0.3 | No |
| Freshwater aquatic community | Chronic | NOEC based on taxonomic richness = 18 ng a.i./L | NOEC = 0.018 | 0.018 | 3.25 (soybean, ground) | 0.014 | 0.8 | No |
| | | | | | 10 (x 8, broccoli, ground) | 0.19 | **11** | **Yes** |
| | | | | | 12.5 (3 x, apples, airblast) | 0.005 | 0.3 | No |
| | | | | | 15 (corn, aerial) | 0.056 | **3.1** | **Yes** |
| Plant | No data available | | | | | | | |
| **Estuarine and Marine Species** | | | | | | | | |
| Marine /estuarine invertebrate | Acute | 7 invertebrate species | HC$_5$ = 0.00012 | 0.00012 | 3.25 (soybean, ground) | 0.014 | **117** | **Yes** |
| | | | | | 10 (x8, broccoli, ground) | 0.19 | **1583** | **Yes** |
| | | | | | 12.5 (3x, apples, airblast) | 0.005 | **42** | **Yes** |
| | | | | | 15 (corn, aerial) | 0.058 | **483** | **Yes** |

| Organism | Exposure | Species | Endpoint reported (µg a.i./L) | Endpoint for RA* (µg a.i./L) | Use Rate** (g a.i./ha) | EEC*** (µg a.i./L) | RQ | LOC exceeded? |
|---|---|---|---|---|---|---|---|---|
| Marine estuarine fish | Acute | Sheepshead minnow (*Cyprinodon variegatus*) | 96-h LC$_{50}$ > 0.49 | 0.049 | 8.25 (soybean, ground) | 0.005 | < 0.1 | No |
| | | | | | 10 (cole, broccoli, ground) | 0.03 | 0.6 | No |
| | | | | | 12.5 (3x, apples, airblast) | 0.0009 | < 0.1 | No |
| | | | | | 15 (corn, aerial) | 0.009 | 0.2 | No |
| Plant | No data available | | | | | | | |

* Endpoints used in the acute exposure risk assessment (RA) are derived by dividing the EC$_{50}$, LC$_{50}$ from the appropriate laboratory study by a factor of two (2) for aquatic invertebrates and plants, and by a factor of ten (10) for fish and amphibians.

The HC$_5$ is the 5th percentile of the species sensitivity distribution for the LC$_{50}$ or NOEC at 50% confidence intervals.

** Application rate represents the minimum and maximum (cumulative) application rates as indicated on labels.

*** EEC based on a 15 cm water body depth for amphibians and a 80 cm water depth for all other aquatic organisms.

Bolded values indicates an exceedance of the level of concern (RQ > 1).

[1] Chronic EEC values represents 90th percentile of the 21 day average for 80 cm deep water body.

[2] Chronic EEC values represent 90th percentile of the 21 day average for 15 cm deep water body.

[3] The acute HC$_5$ for invertebrates (freshwater and marine) are based on data with 48 exposure period and the acute HC$_5$ for fish (freshwater) is based on data with 96 hour exposure periods. For these endpoints, the RQ values shown are based on the peak and 96 hour EECs. For the mesocosm NOEC, the RQ values are based on peak EECs.

## Table 11 Toxic Substances Management Policy Considerations-Comparison to TSMP Track 1 Criteria

| TSMP Track 1 Criteria | TSMP Track 1 Criterion value | | [illegible]<br>Are criteria met? |
|---|---|---|---|
| Toxic or toxic equivalent as defined by the Canadian Environmental Protection Act[1] | Yes | | Yes |
| Predominantly anthropogenic[2] | Yes | | Yes |
| Persistence[3] | Soil | Half-life ≥ 182 days | No: [illegible] days |
| | Water | Half-life ≥ 182 days | No: [illegible] days |
| | Sediment | Half-life ≥ 365 days | Not available |
| | Air | Half-life ≥ 2 days or evidence of long range transport | Half-life or volatilization is not an important route of dissipation and long-range atmospheric transport is unlikely to occur based on the vapour pressure ([illegible] mm Hg at [illegible]) and Henry's Law Constant ([illegible] atm m³/mole). The Atmospheric Oxidation Program (AOPWIN) estimates a photo-chemical oxidative half-life (in the troposphere) in air of [illegible] hours. |
| Bioaccumulation[4] | $\log K_{ow} \geq 5$ | | No: [illegible] |
| | BCF ≥ 5000 | | [illegible] |
| | BAF ≥ 5000 | | Not available |
| Is the chemical a TSMP Track 1 substance (all four criteria must be met)? | | | No, does not meet all TSMP Track 1 criteria |

[1] All pesticides will be considered toxic or toxic equivalent for the purpose of initially assessing a pesticide against the TSMP criteria. Assessment of the toxicity criterion may be refined if required (in other words, all other TSMP criteria are met).

[2] The policy considers a substance "predominantly anthropogenic" if, based on expert judgement, its concentration in the environment medium is largely due to human activity, rather than to natural sources or releases.

[3] If the pesticide and/or the transformation product(s) meet one persistence criterion identified for one media (soil, water, sediment or air) than the criterion for persistence is considered to be met.

[4] [illegible]

# Appendix XII Water monitoring data

A few Canadian studies were available where deltamethrin was analyzed in water samples. Most of the sampling was completed prior to 2002, although a few studies contained data from 2003 – 2007. Deltamethrin has a very wide use pattern; therefore, much of the Canadian data comes from relevant areas.

*United States databases were also searched for monitoring of deltamethrin in water.* Data on residues present in water samples taken in the US are important to consider in the Canadian water assessment given the extensive monitoring programs that exist in the US. Local weather patterns, runoff events, circumstantial hydrogeology as well as testing and reporting methods are probably more important influences on residue data than Northern versus Southern climate. As for climate, if temperatures are cooler, residues may break down more slowly, on the other hand if temperatures are warmer, growing seasons may be longer and pesticide inputs may be more numerous and frequent.

**Discussion and Conclusions**

Of all the Canadian surface water and groundwater samples collected from 1981 to 2007, there were no detections of deltamethrin. There were a total of two detections (0.8 % detection frequency) of deltamethrin from the US data searched, both of which occurred in Californian surface water. Both detections were quite low, 0.004 µg/L (2006) and 0.231 µg/L (2009). Although deltamethrin has high use and an extensive use pattern, it is very uncommon for it to be found in water, largely as a result of its very low solubility in water. The monitoring information is limited, however, based on the limited detections and the environmental fate of this chemical it is expected that the potential exposure of humans and aquatic organisms to deltamethrin will be limited. Chronic exposure of humans and aquatic organisms to deltamethrin in surface water or groundwater is not expected.

## Appendix XIII Label Amendments for Products Containing Deltamethrin

The label amendments presented below do not include all label requirements for individual products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the following label statements.

**I) The following changes must be made to the labels of technical grade deltamethrin:**

> i) The following statement must be included in the section entitled **TOXICOLOGICAL INFORMATION**:
>
> "Skin exposure may cause transient sensations (tingling, burning, itching, numbness). Treat symptomatically."
>
> ii) The following statement must be included in the section entitled **PRECAUTIONS**:
>
> "DO NOT discharge effluent containing this product into sewer systems, lakes, streams, ponds, estuaries, oceans or other waters."
>
> iii) The following statement must be included in a section entitled **ENVIRONMENTAL HAZARDS:**
>
> "TOXIC to aquatic organisms."

**II) The following changes must be made to all end-use product labels containing deltamethrin:**

> i) The following statement must be included in the section entitled **TOXICOLOGICAL INFORMATION**:

"Skin exposure may cause transient sensations (tingling, burning, itching, numbness). Treat symptomatically."

> ii) The following statements must be included in the section entitled **PRECAUTIONS**:
>
> "Workers must wear a respirator with either a NIOSH approved organic vapour-removing cartridge with a prefilter approved for pesticides or a NIOSH approved canister approved for pesticides when mixing, loading and applying deltamethrin using mechanically pressurized handgun equipment."
>
> "Apply only when the potential for drift to areas of human habitation or areas of human activity such as houses, cottages, schools, and recreational areas is minimal. Take into consideration wind speed, wind direction, temperature inversions, application equipment, and sprayer settings."

iii) The following statements must be included in a section entitled **DIRECTIONS FOR USE**:

"Not for use by homeowners or other uncertified users."

"Not permitted for application using a handheld mistblower and/or fogger machine (handheld and automated) in greenhouses."

"The restricted-entry interval is 12 hours after application for all agricultural uses."

"As this product is not registered for the control of pests in aquatic systems, DO NOT use to control aquatic pests."

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

"To protect pollinators, follow the instructions regarding bees in the Environmental Precautions section."

"Field sprayer application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) fine classification. Boom height must be 60 cm or less above the crop or ground."

"Airblast application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** direct spray above plants to be treated. Turn off outward pointing nozzles at row ends and outer rows. **DO NOT** apply when wind speed is greater than 16 km/h at the application site as measured outside of the treatment area on the upwind side."

"Aerial application: **DO NOT** apply during periods of dead calm. Avoid application of this product when winds are gusty. **DO NOT** apply when wind speed is greater than 8 km/h at flying height at the site of application. **DO NOT** apply with spray droplets smaller than the American Society of Agricultural Engineers (ASAE S572.1) fine classification. To reduce drift caused by turbulent wingtip vortices, the nozzle distribution along the spray boom length **MUST NOT** exceed 65% of the wing- or rotorspan."

**Buffer zones (see section 9.1.2):**

"Use of the following spray methods or equipment **DO NOT** require a buffer zone: hand-held or backpack sprayer and spot treatment, or low-clearance hooded or shielded sprayers."

"The buffer zones specified in the table below are required between the point of direct application and the closest downwind edge of sensitive freshwater habitats (such as lakes, rivers, sloughs, ponds, prairie potholes, creeks, marshes, streams, reservoirs and wetlands) and estuarine/marine habitats. "

| Method of application | Crop | Buffer Zones (metres) Required for the Protection of: | | | |
|---|---|---|---|---|---|
| | | Freshwater Habitat of Depths: | | Estuarine/Marine Habitats of Depths: | |
| | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m |
| Field sprayer | Sunflower, rye or wheat cover crop (1 x 5 g a.i./ha) | 5 | 3 | 120 | 120 |
| | HIGH ORGANIC MUCK SOILS: Tomatoes (1 x 7.5 g a.i./ha) | 10 | 4 | 120 | 120 |
| | Canola, mustard, mustard (oilseed), onions, sugar beets, wheat, HIGH ORGANIC MUCK SOILS: Broccoli, brussel sprouts, cabbage, cauliflower (1 x 10 g a.i./ha) | 10 | 5 | 120 | 120 |
| | Alfalfa (seed production only), HIGH ORGANIC MUCK SOILS: Potatoes (1 x 12.5 g a.i./ha) | 10 | 5 | 120 | 120 |
| | Strawberries (2 x 10 g a.i./ha), tobacco (1 x 20 g a.i./ha), soybean, Crop subgroup 5A: Head and stem Brassica, broccoli, brussel sprouts, cabbage, cauliflower, cavolo broccolo, Chinese broccoli, Chinese mustard cabbage (gai choy), kohlrabi, Napa Chinese cabbages (3 x 6.5 g a.i./ha) | 15 | 10 | 120 | 120 |
| | Potatoes, clover, red-established (for seed production only) (2 x 12.5 g a.i./ha), corn, sweet (2 x 15 g a.i./ha), asparagus (3 x 10 g a.i./ha), tomatoes, barley, flax, lentils, oats, wheat, rangeland, pastures, roadsides (3 x 7.5 g a.i./ha) | 20 | 10 | 120 | 120 |
| | Peppers, field corn, seed corn (3 x 15 g a.i./ha) | 30 | 15 | 120 | 120 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | Broccoli, brussel sprouts, cabbage, cauliflower, kale (8 x 10 g a.i./ha) | | 40 | 20 | 120 | 120 |
| | Turf (2 x 60 g a.i./ha) | | 60 | 30 | 120 | 120 |
| Airblast | Peach (1 x 10 g a.i./ha) | Early growth stage | 30 | 20 | 80 | 70 |
| | | Late growth stage | 20 | 10 | 70 | 60 |
| | Blueberries (3 x 7.5 g a.i./ha) | Early growth stage | 40 | 30 | 85 | 80 |
| | | Late growth stage | 30 | 20 | 75 | 65 |
| | Saskatoon berries (3 x 10 g a.i./ha) | Early growth stage | 40 | 30 | 90 | 80 |
| | | Late growth stage | 30 | 20 | 80 | 70 |
| | Apples (3 x 12.5 g a.i./ha) | Early growth stage | 45 | 35 | 90 | 85 |
| | | Late growth stage | 35 | 25 | 80 | 70 |
| | Pears (3 x 17.5 g a.i./ha) | Early growth stage | 45 | 35 | 95 | 85 |
| | | Late growth stage | 35 | 25 | 85 | 75 |

## Aerial Buffer Zones for Reg. No. 17734 – ASAE Fine

| Method of application | Crop | Buffer Zones (metres) Required for the Protection of: | | | |
|---|---|---|---|---|---|
| | | Freshwater Habitat of Depths: | | Estuarine/Marine Habitats of Depths: | |
| | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m |

| | | | | | | |
|---|---|---|---|---|---|---|
| Aerial | Sunflowers (1 x 5 g a.i./ha) | Fixed wing | 95 | 15 | 800 | 800 |
| | | Rotary wing | 85 | 10 | 800 | 800 |
| | Canola, mustard, mustard (oilseed), rapeseed, flax, potatoes (high organic muck soils) (1 x 7.5 g a.i./ha) | Fixed wing | 250 | 40 | 800 | 800 |
| | | Rotary wing | 125 | 25 | 800 | 800 |
| | Canola, mustard, mustard (oilseed), rapeseed (1 x 10 g a.i./ha) | Fixed wing | 300 | 65 | 800 | 800 |
| | | Rotary wing | 150 | 45 | 800 | 800 |
| | Barley, flax, lentils, oats, sugarbeets, wheat, pastures, rangelands, potatoes (2 x 7.5 g a.i./ha) | Fixed wing | 425 | 150 | 800 | 800 |
| | | Rotary wing | 200 | 90 | 800 | 800 |

**Aerial Buffer Zones for Reg. No. 20078 – ASAE Fine**

| Method of application | Crop | | Buffer Zones (metres) Required for the Protection of: | | | |
|---|---|---|---|---|---|---|
| | | | Freshwater Habitat of Depths: | | Estuarine/Marine Habitats of Depths: | |
| | | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m |
| Aerial | Canola, mustard, mustard (oilseed), rapeseed (1 x 7.5 g a.i./ha) | Fixed wing | 150 | 30 | 800 | 800 |
| | | Rotary wing | 200 | 30 | 800 | 800 |
| | Barley, flax, lentils, oats, wheat, pastures, rangelands (2 x 6.0 g a.i./ha) | Fixed wing | 250 | 55 | 800 | 800 |
| | | Rotary wing | 275 | 50 | 800 | 800 |

**Aerial Buffer Zones for Reg. No. 22478 – ASAE Fine**

| | | Buffer Zones (metres) Required for the Protection of: | |
|---|---|---|---|
| | | Freshwater Habitat of Depths: | Estuarine/Marine Habitats of Depths: |

| Method of application | Crop | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m |
|---|---|---|---|---|---|---|
| Aerial | Sunflowers (1 x 5 g a.i./ha) | Fixed wing | 95 | 15 | 800 | 800 |
| | | Rotary wing | 85 | 10 | 800 | 800 |
| | Canola (rapeseed), mustard, potatoes (high organic muck soils) (1 x 7.5 g a.i./ha) | Fixed wing | 250 | 40 | 800 | 800 |
| | | Rotary wing | 125 | 25 | 800 | 800 |
| | Barley, flax, lentils, oats, wheat, corn, sweet (high organic muck soils) (1 x 10 g a.i./ha) | Fixed wing | 300 | 65 | 800 | 800 |
| | | Rotary wing | 150 | 45 | 800 | 800 |
| | Barley, flax, lentils, oats, wheat, pastures, rangelands, potatoes (2 x 7.5 g a.i./ha), corn, sweet (1 x 15 g a.i./ha) | Fixed wing | 375 | 175 | 800 | 800 |
| | | Rotary wing | 175 | 75 | 800 | 800 |

## Aerial Buffer Zones for Reg. No. 25573 – ASAE Fine

| Method of application | Crop | | Buffer Zones (metres) Required for the Protection of: | | | |
|---|---|---|---|---|---|---|
| | | | Freshwater Habitat of Depths: | | Estuarine/Marine Habitats of Depths: | |
| | | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m |
| Aerial | Sunflowers (1 x 5 g a.i./ha) | Fixed wing | 75 | 15 | 800 | 800 |
| | | Rotary wing | 75 | 10 | 800 | 800 |
| | Canola (rapeseed), | Fixed wing | 150 | 30 | 800 | 800 |

| | | | | | | |
|---|---|---|---|---|---|---|
| | mustard, potatoes (high organic muck soils) (1 x 7.5 g a.i./ha) | Rotary wing | 200 | 30 | 800 | 800 |
| | Barley, flax, lentils, oats, wheat, corn, sweet (high organic muck soils (1 x 10 g a.i./ha) | Fixed wing | 450 | 35 | 800 | 800 |
| | | Rotary wing | 225 | 30 | 800 | 800 |
| | Barley, lentils, flax, oats, wheat, rangelands, pastures, potatoes (2 x 7.5 g a.i./ha), corn, sweet (1 x 15 g a.i./ha) | Fixed wing | 500 | 200 | 800 | 800 |
| | | Rotary wing | 250 | 125 | 800 | 800 |

**Aerial Buffer Zones for Reg. No. 29611 – ASAE Fine**

| Method of application | Crop | | Buffer Zones (metres) Required for the Protection of: | | | |
|---|---|---|---|---|---|---|
| | | | Freshwater Habitat of Depths: | | Estuarine/Marine Habitats of Depths: | |
| | | | Less than 1 m | Greater than 1 m | Less than 1 m | Greater than 1 m |
| Aerial | Soybean (3 x 6.5 g a.i./ha) | Fixed wing | 500 | 250 | 800 | 800 |
| | | Rotary wing | 250 | 125 | 800 | 800 |

For tank mixes, consult the labels of the tank-mix partners and observe the largest (most restrictive) buffer zone of the products involved in the tank mixture and apply using the coarsest spray (ASAE) category indicated on the labels for those tank mix partners.

The buffer zones for this product can be modified based on weather conditions and spray equipment configuration by accessing the Buffer Zone Calculator on the Pest Management Regulatory Agency web site. Buffer zones of 120 m (field sprayer) or 800 m (aerial sprayer) CANNOT be modified.

iv) In order for use directions of deltamethrin products to be consistent with the assumptions used in the PMRA health risk assessment, labels must be updated to include this information under **DIRECTIONS FOR USE**, as applicable:

a. For labels containing use directions for broccoli, Brussels sprouts, cabbage and cauliflower, under the use directions for broccoli, Brussels sprouts, cabbage and cauliflower, add the following statement:

"DO NOT APPLY MORE THAN 8 TIMES PER YEAR" immediately after the sentence: "Repeat every 10 days as necessary."

b. For labels containing use directions for kale, under the use directions for kale, add the following statement:

"DO NOT APPLY MORE THAN 8 TIMES PER YEAR" immediately after the sentence: " Repeat every 10 days as necessary."

c. For labels containing use directions for asparagus, under the use directions for asparagus, add the following statement:

"DO NOT APPLY MORE THAN 3 TIMES PER YEAR" immediately after the sentence: " Repeat as needed."

d. For labels containing use directions for blueberries, under the use directions for blueberries, add the following statement:

"DO NOT APPLY MORE THAN 3 TIMES PER YEAR" immediately before the sentence: "Apply to lowbush blueberries in 100-200 litres of water per hectare."

e. For labels containing use directions for tobacco, under the use directionsfor tobacco, add the following statements:

"DO NOT APPLY MORE THAN 3TIMES PER YEAR IN GREENHOUSE" under the "GREENHOUSE" immediately after the sentence: "Plants should be sprayed in the evening".

"DO NOT APPLY MORE THAN ONCE PER YEAR IN FIELD." immediately after the statement: "DO NOT apply within 45 days of harvest (PCP # 22478) and DO NOT apply within 70 days of harvest."

v) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS** :

"TOXIC to aquatic organisms. Observe buffer zones specified under DIRECTIONS FOR USE."

"TOXIC to bees. Minimize spray drift to reduce harmful effects on bees in habitats close to the application site. DO NOT apply this product to blooming crops or weeds while bees are actively foraging in the treatment area. Application during the crop blooming period, and when blooming weeds are present may be made in the early morning or the late evening when most bees are not actively foraging. To further minimize exposure to pollinators, refer to the complete guidance "Protecting Pollinators during Pesticide Spraying – Best Management Practices" on the Health Canada website (www.healthcanada.gc.ca/pollinators)."

"Toxic to certain beneficial insects. Minimize spray drift to reduce harmful effects on beneficial insects in habitats next to the application site such as hedgerows and woodland."

"To reduce runoff from treated areas into aquatic habitats avoid application to areas with a moderate to steep slope, compacted soil, or clay."

"Avoid application of this product when heavy rain is forecast."

"Contamination of aquatic areas as a result of runoff may be reduced by including a vegetative strip between the treated area and the edge of the water body."

III) The following statements must be included in a section entitled **ENVIRONMENTAL HAZARDS** on labels of end use products with **greenhouse uses**:

"Toxic to bees and other beneficial insects. May harm bees and other beneficial insects used in greenhouse production. Avoid application when bees or other beneficial insects are actively foraging in the treatment area."

"DO NOT allow effluent or runoff from greenhouses containing this product to enter lakes, streams, ponds or other waters."

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| 1549419/1561475 | Metabolism Of [14C-Acid] And [14C-Alcohol] Decis (Deltamethrin) In Field Corn. |
| 1549421/1561485 | Preliminary Uptake - Translocation Studies Of Ru 22974 In Cotton. |
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| 1549425/1561429 | Degradation Of Decamethrin On Cotton Plants |
| 1549426 | Analysis Of Metabolites In Tissues Following Administration Of 14C- Gem-Dimethyl Tralomethrin In Lactating Dairy Cattle. Supplement To MRID 42137506. |
| 1549427 | (Deltamethrin): "Metabolism Of 14C Benzyl-Tralomethrin And 14C-Gem-Dimethyl-Tralomethrin In Laying Hens" - (Supplement 1). |
| 1549428 | Metabolism Of 14C-Benzyl-Tralomethrin And 14C-Gem-Dimethyl-Tralomethrin In Lactating Dairy Cattle And Storage Stability Of Tralomethrin And Deltamethrin In Cow Milk And Tissues. |
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| 840947 | Supplement To The Report (Amendment): 14C-Deltamethrin: Confined Accumulation In Rotational Crops 30-Day Experiment. (Analytical Phase). |
| 840948 | C-14 Deltamethrin: Confined Accumulation In Rotational Crops 30 And 120 Day Experiment |
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| 840953/1136935 | Fate Of 14C Deltamethrin In Lactating Dairy Cows. |
| 840954/2143235 | Feeding Study Of A Mixture Of Tralomethrin And Deltamethrin In Dairy Cows And Magnitude Of The Combined Residues Of Tralomethrin, Deltamethrin, And Trans-Deltamethrin In Milk And Tissues Of Dairy Cattle (Amendment To Report Number HR-01-88) |
| 840955 | Feeding Study Of A Mixture Of Tralomethrin And Deltamethrin In Dairy Cows And Magnitude Of The Combined Residues Of Tralomethrin, Deltamethrin And Trans-Deltamethrin In Milk And Tissues Of Dairy Cattle (Amendment To Report Number HR-01-88) |
| 840956/1561467 | Feeding Study Of A Mixture Of Tralomethrin And Deltamethrin In Dairy Cows And Magnitude Of The Combined Residues Of Tralomethrin, Deltamethrin And Trans-Deltamethrin In Milk And Tissues Of Dairy Cattle. (2 Volumes). |
| 840959 | Amended Summary Report Covering Submission Guidelines For Magnitude Of The Residue (171-4(K)), Processed Food/Feed (171-4(L)), Residue Methodology (171-4(C)) And Storage Stability (171-4(E)) For Residues Of Deltamethrin And Its Metabolites Trans-Deltameth |
| 840960/1561446 | Determination Of Freezer Residue Stability For Deltamethrin (Alpha-R, Cis, And Trans) And Tralomethrin In Poultry Tissues. |
| 840961/1561483 | Supplement To: Determination Of The Combined Residues Of Tralomethrin, Deltamethrin And Trans-Deltamethrin In Lettuce In A Freezer Stability Study. |
| 840962/1561449 | Development Of An Analytical Procedure For Confirming Residues Of Cis-, Trans-, And Alpha-R Deltamethrin In Representative Sample Extracts Generated Using Hoechst Method HRAV-20 (Crop Samples) And HRAV-22 (Animal Tissue Samples). |
| 840963/1561470 | Analytical Method For The G.C. Determination Of Cis-Deltamethrin, Trans-Deltamethrin And Alpha-R-Deltamethrin In Selected Processed Grain Fractions, Grain Dusts And Whole Grain From Corn, Wheat, Sorghum And Rice. |
| 840964/1561471 | Method Development And Validation For The Determination Of Deltamethrin (Alpha-R-, Cis- And Trans-) And Tralomethrin In Dairy Cow Tissues (With Poultry Matrices Added By Amendment). |
| 840965/1561512 | Analytical Methodology For The Analysis Of Cis-, Trans-, And Alpha-R-Deltamethrin In Soybean Seeds And Processed Fractions. |
| 840966/1561514 | PR Notice 88-5 Enforcement Method Validation For Tralomethrin, Cis-Deltamethrin, Trans-Deltamethrin And Alpha-R-Deltamethrin In The Raw Agricultural Commodities Of Milk, Eggs (York And White), Chicken Muscle, Beef Muscle, Beef Liver And Beef Fat. Mckenzie Laboratories Inc., Phoenix, Arizona. 2/18/1994. Study #93-0019. Document # A73905. GLP |
| 840967 | Chronic And Acute Dietary Exposure Analyses And Risk Assessments Deltamethrin And Tralomethrin |
| 840968/1561459 | Magnitude Of The Residue Of Deltamethrin In Stored Food |
| 840969/1561670 | Summary Report Covering Submission For Magnitude Of Residue, Processed Food/Feed, Storage Stability And Residue Methodology For Residues Of Deltamethrin And Metabolites, Trans-Deltamethrin And Alpha-R-Deltamethrin In Cotton. |
| 840970 | Synthetic Pyrethroids : Generic Methodology For Dietary Risk Assessment. |
| 840971 | Deltamethrin: European Community Data Summary - Residues In Or On Treated Products, Food And Feed |
| 840972/1561523 | Independent Method Validation Ruggedness Trial For Determination Of Deltamethrin In Grain Crops Using Roussel- Uclaf Analytical Method No. ENC-6/92 And Roussel-Uclaf Analytical Method No. ENC-8/92 - Deltamethrin. |

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| 840973 | Supplement To: Validation Of Proposed Analytical Method For The Analysis Of Cis-Deltamethrin And Trans-Deltamethrin In Various Crop Matrices: Amendment To Validation Report N.1 (Cottonseed & Cottonseed Fractions); Determination Of The Specificity Of Analy |
| 840974/1561448 | Method Validation For The Determination Of Deltamethrin (Alpha-R, Cis, And Trans) And Tralomethrin In Milk Fat. |
| 840975/1561469 | Validation Of The Analytical Methodology For Determination Of Combined Residues Of Deltamethrin & Trans-Deltamethrin In Cottonseed & Cottonseed Processed Fractions. |
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| 840977/1561649 | Stability Of Tralomethrin, Cis-Deltamethrin And Trans-Deltamethrin In Cottonseed Under Freezer Storage Conditions [With Alpha-R-Deltamethrin And Stability In Processed Commodities (Cottonseed Fractions) Added By Amendment] |
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| 840979/1561447 | Magnitude Of The Residue Of Scout X-Tra (TM) Insecticide In Or On Wheat Grain And Processed Commodities. |
| 840980/1561473 | The GLC Determination Of The Combined Residues Of Deltamethrin And Trans-Deltamethrin In Mexican Cherry Tomatoes. |
| 840981/1561489 | Magnitude Of The Combined Residues Of Deltamethrin, Trans-Deltamethrin And Alpha-R-Deltamethrin On Cottonseed Raw Agricultural Commodity (RAC). |
| 840982/1561491 | Determination Of Residues Of Deltamethrin And Its Metabolites Trans-Deltamethrin And Alpha-R-Deltamethrin In Cottonseed Samples And Analysis Of Cotton Matrices Resulting From Application Of IS- 002A Or IS-002B Insecticides: Amendment To Analysis Report No |
| 840983/1561493 / 1449943 | Application Of Decis 2.5 EC Insecticide On Soybeans And Collection Of Harvest Samples For The Determination Of Cis-Deltamethrin And Its Metabolites Trans-And Alpha-R-Deltamethrin In Soybean Seed. |
| 840985/1561502 | Wheat Grain (Seed) Treatment, Generation, Collection Of Processed Fractions To Determine Residue Level Of Deltamethrin, (S)- Alpha-Cyano-M-Phenoxybenzyl (1R, 3R)-3 (2,2-Dibromovinyl)-2, 2-Dimethyl Cyclopropane Carboxylate. |
| 840986/1561503 | Sorghum Grain (Seed) Treatment, Generation, Collection Of Processed Fractions To Determine Residue Levels Of Deltamethrin, (S)- Alpha-Cyano-M-Phenoxybenzyl (1R, 3R)-3 (2,2-Dibromovinyl)-2,2-Dimethyl Cyclopropane Carboxylate. |
| 840987/1561504 | Corn Grain (Seed) Treatment, Generation, Collection Of Processed Fractions To Determine Residue Level Of Deltamethrin, (S)- Alpha-Cyano-M-Phenoxybenzyl (1R, 3R)-3 (2,2-Dibromovinyl)-2, 2-Dimethyl Cyclopropane Carboxylate. |
| 840988/1561505 | Rice Grain (Seed) Treatment, Generation, Collection Of Processed Fractions To Determine Residue Level Of Deltamethrin, (S)- Alpha-Cyano-M-Phenoxybenzyl (1R, 3R)-3 (2,2-Dibromovinyl)-2, 2-Dimethyl Cyclopropane Carboxylate. |
| 840989/1561510 | Magnitude Of The Residue Of Scout X-Tra Insecticide In Wheat. |
| 840990 | Decis Liquid (Emusifiable Concentrate): Determination Of Deltamethrin Residues In Green Hops And Dried Hops. |
| 840991/1561518 | LX165-12 (Decis 2.5 EC) Raw Agricultural Commodity Residue Evaluation Of Cis-, Trans- And Alpha-R-Deltamethrin From Decis 2.5 Applied To Cucumber, Cantaloupe, And Squash In Mexico. |
| 840992/1561519 | LX165-12 (Decis 2.5 EC) Raw Agricultural Commodity Residue Evaluation Of Cis-, Trans- And Alpha-R-Deltamethrin From Decis 2.5 Applied To Cucumber, Cantaloupe, And Squash In Canada. |
| 840993/1561525 | LX165-12 (Decis 2.5 EC) Raw Agricultural Commodity Residue Evaluation Of Cis-, Trans- And Alpha-R-Deltamethrin Resulting From Decis EC 2.5 Applied To Cucumber, Cantaloupe And Squash In United States - Deltamethrin. |
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| 840995 | Residue Determination Of Deltamethrin On Wheat Grain And Wheat Dust Following Treatment Of Wheat With Deltamethrin Grain Protectant And Water (Or Oil Carriers) Deltamethrin |
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| 841004/1561542 | Magnitude Of Deltamethrin Residues In Or On Peaches Resulting From Three Applications Of Decis (R) Insecticide USA, 1998 |
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| 841011/1449948 | At Harvest Deltamethrin-Derived Residues In Tomatoes Following Six Applications Of DECIS (R) At The Maximum Proposed Rate And The Shortest Proposed PHI, USA, 1998 (Interim Report) |
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| 1055311 | Deltamethrin PMRA Deficiency Review. Decis 5EC - PMRA Review Comments; Part 7 Food, Feed And Tobacco Residue Studies. Includes Attachments. |
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| 1083626/1083623/1561672 | Determination Of Insecticide Residues In Canola Following A Late Season Application Of Decis 5 EC And Decis Flowable Insecticides |
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| 1136386 | Crop Residue Data On Sugar Beets And Snap Beans (Decis 5.0ec).[Vol.No.:74;Dec/90] |
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| 1136938 | Residue Data For Crops Used In 1987 Study Of Residue In Milk & Tissue Of Lactating Dairy Cows (By M. Akhtar Et Al.)(Decis 2.5 Ec/ 5.0ec) |
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| 1136941 | Residue Data For Crops Used As Livestock Feed Of Decis 2.5 Ec/ 5.0ec On Red Clover, Kale, Lentils, Spring Rye And Triticale |
| 1145379 | Determination Of Deltamethrin In Various Crops (Ou89-03)(Barley,Brussprout,Canola,Sweet Corn,Lentil,Oats,Peach,Potato,Wheat)(Decis 2.5 And 5.0ec/Decis 5.0 Flowable) |
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| 1162838 | Additional Milk Fat Data Requested By T. Caunter (P.M.R.A) (October 30 1995)(Research Permit 95-115)(Deltramethrin Pour On) |
| 1167425 | Residue Data In Support Minor Use# 92-110 Deltamethrin In Onions (Pesa: Onion Thrips)(May 1996)(Decis 2.5ec) |
| 1182977 | Carbon-14 Residues In Biological Samples Of Lactating Cows Fed 14c-Deltamethrin, August 8, 1985 [Deltamethrin] |
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| 1204921 | Food, Feed & Tobacco Residue Studies - Summary |
| 1204922 | Methodology. M Jorgensen |
| 1204923 | Individual Data On Residues - Alfalfa. |
| 1204925 | Individual Data On Residues - Barley. |
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| 1205984 | Residue Analysis - Cole Crops - Broccoli. |
| 1205999 | Residue Analysis - Cole Crops - Soil. |
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